

EXHIBIT P

Exhibit P – SEALED excerpts of Plaintiffs’ Expert Witness A. Kolodny
Transcript of Deposition (Sept. 04, 2020)

PLAINTIFFS’ OPPOSITION TO DEFENDANTS’ MOTION TO EXCLUDE MARKETING
OPINIONS OF DRs. ANNA LEMBKE, KATHERINE KEYES, ANDREW KOLODNY, AND JAKKI
MOHR

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

- - - - - x

THE CITY OF HUNTINGTON,
Plaintiff,
vs. Civil Action No.
3:17-01362

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

- - - - - x

CABELL COUNTY COMMISSION,

Plaintiff,

vs. Civil Action No.
3:17-01665

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

- - - - - x

September 4, 2020
9:00 a.m.

VIDEO RECORDED DEPOSITION of ANDREW KOLODNY, M.D., an
Expert Witness for the Plaintiff herein, held remotely via
Zoom before Sara K. Killian, a Registered Professional
Reporter, Certified Court Reporter and Notary Public of
the State of New York.

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20 (Continued on following page)
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1 A P P E A R A N C E S: (cont'd)

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25 (Continued on following page)

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1 THE VIDEOGRAPHER: I am now
2 recording. The time is 9:06 and we are on
3 the record. This is the videographer
4 speaking, Geoffrey C. Bassett, with Veritext
5 Legal Solutions -- sorry guys, my
6 apologies -- with Veritext Legal Solutions.

7 Today's date is September 4th, 2020
8 and the time is 9:06 a.m. We're here to take
9 the remote video deposition of Dr. Andrew
10 Kolodny in the matter of City of Huntington
11 versus AmerisourceBergen Drug Corporation, et
12 al.

13 Would counsel please introduce
14 themselves for the record?

15 MS. DICKINSON: Sure. Erin Dickinson
16 at Crueger Dickinson for the plaintiffs and
17 along with me is Anthony Majestro, also for
18 the plaintiffs.

19 MR. HESTER: This is Timothy Hester.
20 I represent McKesson for the defendant
21 McKesson and with me are Emily Ullman and
22 James Goold from Covington & Burling.

23 MR. FRANKS: Ray Franks. I'm local
24 counsel in Charleston, West Virginia for
25 Cardinal Health with the law firm of Carey

1 Douglas Kessler & Ruby.

2 MS. MCNAMARA: And this is Colleen
3 McNamara from Williams & Connelly, also on
4 behalf of Cardinal Health.

5 MS. VITALE: This is Christina Vitale
6 with Reed Smith on behalf of defendant
7 AmerisourceBergen Drug Corporation and along
8 with me is Alyssa Conn.

9 MR. HESTER: Good morning, Dr.
10 Kolodny. I introduced myself already, but
11 again, my name is --

12 THE COURT REPORTER: I have to swear
13 in the witness still.

14 MR. HESTER: Oh, sorry.

15 THE VIDEOGRAPHER: So if everyone has
16 been introduced, will the court reporter,
17 Sara Killian, please swear in the witness.
18 Thank you.

19 A N D R E W K O L O D N Y, M. D., after having
20 first been duly sworn by a Notary Public, was
21 examined and testified as follows:

22 THE COURT REPORTER: Please state
23 your name and address for the record.

24 THE WITNESS: Dr. Andrew Kolodny,
25 4658 Hanford Street, Douglaston, New York.

1 EXAMINATION BY

2 MR. HESTER:

3 Q. Good morning, Dr. Kolodny. I
4 introduced myself before. My name is Tim Hester.
5 I represent McKesson.

6 Let me just set a few ground rules.
7 Since we're doing this deposition remotely, it's a
8 little bit more unusual than if we were face to
9 face.

10 Are you in your office now?

11 A. I am.

12 Q. And is there anybody else there with
13 you?

14 A. No. Not in my office.

15 Q. We had sent you exhibits previously
16 in a box that you opened this morning, correct?

17 A. That's correct.

18 Q. Are there any other papers that you
19 have with you that you are going to be consulting
20 today, aside from the exhibits I show you?

21 A. Not in the office with me.

22 (Whereupon, Exhibit 1 was marked for
23 identification.)

24 Q. Okay.

25 Dr. Kolodny, let me ask you to open

1 up Exhibit 1, which is in the envelopes, I think,
2 behind you.

3 Do you recognize this document?

4 A. I do.

5 Q. It's a copy of your report that
6 you've submitted in this litigation; is that
7 right?

8 A. That's correct.

9 Q. And we've premarked that as Exhibit 1
10 for the record.

11 Dr. Kolodny, let me ask you first are
12 you stating -- the opinions that are reflected in
13 this report, are those the opinions you're
14 offering in this litigation?

15 A. This report contains opinions that I
16 will be offering in this litigation or that I am
17 offering in this litigation.

18 Q. Are there any opinions that you're
19 intending to offer in the litigation that are not
20 set out in the report?

21 A. It's possible. Not that I can
22 immediately think of.

23 Q. Okay.

24 And I recognize you've been working
25 in this field for a long time, but I wanted to ask

1 you about any specific studies or specific facts
2 you're relying on for purposes of your opinions.

3 Are there any specific facts or
4 specific studies you're relying on that are not
5 set out in the report?

6 A. Probably.

7 Q. Do you have those in mind?

8 A. I don't know that it would be
9 possible for me to think of them in advance. I've
10 been working on the opioid crisis for 17 years.
11 I've been studying it, writing about it, reading
12 about it and I think it's very likely there are
13 many specific facts that are important but that I
14 didn't wind up getting included. It's impossible
15 to really think of everything in advance that
16 might inform my opinion.

17 Q. Are there any specific studies you're
18 planning to rely on to support your opinions that
19 are not cited or referred to in the report?

20 A. It's possible, but none that I
21 thought of in advance of writing the report and
22 didn't include, but it's very likely there are
23 many specific studies that inform my opinion that
24 didn't make it into this report.

25 Q. You don't have any in mind as you sit

1 here that you would intend to rely on?

2 A. No, I don't. If you were to -- if
3 you start asking me about different subjects, I
4 could probably at that point think of articles,
5 you know, research that's been done that would be
6 relevant to my opinion that didn't make it into
7 this report, but there's nothing I could think of
8 right now off the top of my head that didn't make
9 it into the report.

10 Q. Okay.

11 Do you have any corrections to make
12 to the report?

13 A. There -- yeah. I think Ms. Dickinson
14 sent a correction to the report I believe
15 yesterday. It might have been a missing citation.

16 And as I've gone through the report,
17 just in preparation, I've found typos in different
18 places. For example, there was a -- in one place
19 where I used the word Oxycontin and I meant the
20 word -- I meant to say Oxycodone.

21 MS. DICKINSON: For the record, just
22 for the record, the correction that we sent
23 over, the errata, was to footnote 318 and it
24 was missing a citation and we provided that
25 citation and so that correspondence should be

1 deemed an errata to his actual report.

2 MR. HESTER: We did receive that.

3 Q. Are there any other errata you intend
4 to make at this stage? I understand there may be
5 typos. I'm asking about substantive changes.

6 A. I don't think so.

7 Q. Okay.

8 Do you know roughly the amount that
9 you've been paid to date for testifying in these
10 various opioid litigations?

11 A. I don't have a number off the top of
12 my head. I would -- yeah. So, I mean, are you
13 talking about since -- do you have a time frame
14 that you're referring to?

15 Q. Well, I believe you've been an expert
16 in three of the opioid litigations -- is that
17 right? -- in Ohio, in Oklahoma and now this matter
18 in West Virginia.

19 A. Yes, that's correct.

20 Q. And I was just trying to get a range
21 of magnitude. Roughly speaking, what's the range
22 of magnitude of the total amount you've been paid
23 as a testifying expert in those three cases?

24 A. I think I started working for -- I
25 think I worked for Oklahoma about two years, more

1 or less, and I can't really remember the exact
2 date, but I would estimate over a three- to
3 four-year period of working on the opioid
4 litigation -- it would be a three-year period --
5 total revenue earned would probably -- ballpark
6 500,000, more or less. Maybe more. Probably 500
7 to 600 I would say over a three-year period.

8 Q. Is your compensation in any way
9 dependent on the outcome of this litigation?

10 A. No.

11 Q. So there's no bonus or extra
12 compensation you receive depending on the outcome?

13 A. That's correct.

14 Q. Let me ask you first to discuss the
15 issue of pain treatment.

16 Dr. Kolodny, do you agree that the
17 treatment of pain in a legitimate medical issue?

18 MS. DICKINSON: Object to the form.

19 A. Yes.

20 (Whereupon, Exhibit 3 was marked for
21 identification.)

22 Q. And let me ask you to look at
23 Exhibit 3, please, if you could open that. Sorry
24 for the mechanics of having to do this.

25 A. That's okay. I've got it.

1 Q. Okay.

2 Exhibit 3, which we premarked, is
3 entitled "CDC Guideline for Prescribing Opioids
4 for Chronic Pain, United States, 2016."

5 Dr. Kolodny, have you seen this
6 document before?

7 A. I have.

8 Q. And you cite it in your report,
9 correct?

10 A. I do.

11 Q. Let me ask you to look at page one,
12 please, of the guidelines and it's in the
13 paragraph on page one on the right-hand side, the
14 first full sentence, which reads "Patients can
15 experience persistent pain that is not well
16 controlled."

17 Do you agree with that as a doctor?

18 A. I'm sorry. Where are you?

19 Q. I'm sorry. It's the right-hand
20 column on the first page and it's the first
21 sentence.

22 Do you see where it says "Patients
23 can experience persistent pain that is not well
24 controlled"?

25 A. So the -- I'm sorry. The first

1 page -- do you mean the page marked one or do you
2 mean the actual first page?

3 Q. Oh, sorry. I didn't realize you had
4 an extra page there. So it would be the first
5 substantive page of text under the heading
6 "Introduction."

7 A. Yes. I've got that now. Okay.

8 Q. Okay. It's page one of the document.
9 Do you see that?

10 A. Yes.

11 Q. And I wanted to point you to the
12 right-hand column --

13 A. Yes.

14 Q. -- the first full sentence. It says
15 "Patients can experience persistent pain that is
16 not well controlled."

17 Do you see that?

18 A. I do.

19 Q. Do you agree with that?

20 A. Yes, I do.

21 Q. Do you see the next sentence: "There
22 are clinical psychological and social consequences
23 associated with chronic pain"?

24 Do you see that?

25 A. I do.

1 Q. Do you agree with that?

2 A. I do.

3 Q. And let me ask you to turn to page
4 two of the document. At the top of the left-hand
5 column, the first full sentence says "Most
6 recently, analysis of data from the 2012 National
7 Health interview studies showed that 11.2% of
8 adults report having daily pain."

9 Do you see that?

10 A. I do.

11 Q. Do you agree with that?

12 A. I would want to look at the citation.
13 I do believe that experiencing pain on a regular
14 basis is very common. Feeling aches and pains is
15 part of being alive and I do -- I wouldn't -- the
16 estimate of 11.2% wouldn't surprise me, that 11.2%
17 of adults on a routine basis have daily pain.

18 Q. Right.

19 Let me ask you next do you agree that
20 prescription opioids can address legitimate
21 medical needs in treating pain?

22 A. You know, I think that opioids can be
23 effective for treating pain at the end of life
24 when you're able to continue increasing the dose
25 because someone is near the end of life and I

1 think opioids can be effective for pain when used
2 intermittently, low doses. But I do not believe
3 opioids are effective for pain when they're taken
4 around the clock for weeks and months and years
5 unless the dose keeps going up.

6 Q. Okay. Let me ask you to look at your
7 report, please, Exhibit 1, page nine.

8 Do you have that there, page nine?

9 A. I do.

10 Q. Do you see the second full paragraph
11 begins "Opioids are essential medicines for
12 palliative care"?

13 A. Yes.

14 Q. Why are they essential medicines for
15 that purpose?

16 A. Because near the end of life, when
17 you're able to continue increasing the dose
18 because someone is near the end of life and you
19 don't have to worry so much about addiction or
20 respiratory depression or even the opioid
21 potentially shortening the life span for someone
22 who is near the end of life and suffering, they
23 can be effective and they can provide relief and
24 not only do opioids relieve the physical pain, but
25 they can also provide a sense of wellbeing for

1 someone who is scared and suffering near the end
2 of life.

3 Q. Let me ask you to look at page 11,
4 please, of your report.

5 A. Yes.

6 Q. Do you see the third paragraph? The
7 first sentence refers to the legitimate use of
8 opioids -- and I'm now going to quote -- for acute
9 pain, cancer pain, palliative care and
10 catastrophic injury.

11 Do you see that?

12 A. You're at the third paragraph --

13 Q. Yes. I wanted to ask you about this
14 phraseology that you used where you refer to the
15 legitimate use of --

16 A. Can you just -- I'm on page 11.

17 Q. Sorry. It's the third paragraph. It
18 begins "Industry joined together ..."

19 Do you see that paragraph?

20 A. I see that first sentence.

21 Q. Yes.

22 Do you see where you use the phrase
23 "legitimate use"? It's in the second line of that
24 paragraph.

25 A. I do.

1 Q. And you refer in there to the
2 legitimate use for prescription opioids.

3 A. Yes.

4 Q. And you say the legitimate use for
5 prescription opioids is for acute pain, cancer
6 pain, palliative care and catastrophic injury; is
7 that correct?

8 A. That's correct.

9 Q. And why do you say those are
10 legitimate uses?

11 A. I think -- and let me just clarify
12 that, you know, when I say legitimate, I'm
13 really -- what I'm referring to is appropriate
14 uses, so these are appropriate uses because for
15 these different conditions, the benefits of an
16 opioid can outweigh the risks and so with any
17 medical treatment, if the benefits outweigh the
18 risks for that individual patient, then the
19 treatment generally would be considered
20 appropriate.

21 Q. Do you know what share of
22 prescription opioids are used for these legitimate
23 uses or appropriate uses?

24 A. Yes, I do and it really depends on
25 how you're measuring the share for consumption.

1 If you're measuring consumption by numbers of
2 prescriptions written, acute pain constitutes a
3 large percentage of the number of prescriptions
4 written. If you're measuring consumption in terms
5 of morphine milligram equivalents, chronic pain,
6 chronic non-cancer pain, conditions for which the
7 risks of opioids outweigh the benefit constitute
8 the bulk of consumption.

9 When it comes to cancer pain, at
10 least for Hydrocodone combination products, my
11 understanding -- the data I've seen on this is
12 that cancer constitutes about 2%, neoplasms
13 constitute about 2% of opioid prescriptions
14 written.

15 Q. So when you said that the largest
16 share of prescriptions written is for acute pain,
17 do you have in mind a number on that or a
18 percentage?

19 A. Not off the top of my head. I want
20 to have some real data in front of me.

21 Q. I mean, is it two-thirds?

22 A. I don't really want to guess, but
23 it's a very large percentage are written in a
24 small quantity for acute pain.

25 Q. When you say large percentage, do you

1 mean more than 50% of prescriptions are written
2 for acute pain?

3 A. I believe that's correct. I think
4 more than half of prescriptions are written for
5 acute pain.

6 Q. And you said roughly 2% of
7 prescriptions you believe are written for cancer
8 pain?

9 A. I've seen data on Hydrocodone
10 combination products that show that about 2% are
11 for cancer.

12 Q. And for catastrophic injury that you
13 refer to here, are you putting that in the
14 category of acute pain or is that something
15 different?

16 A. Acute pain would include hospital
17 use, during surgery or immediately after surgery
18 or someone who has arrived in an emergency room,
19 experiencing a catastrophic injury. Those are
20 circumstances in which opioids are appropriate for
21 acute pain.

22 I should point out, though, that when
23 we talk about acute pain and the percentage of
24 prescriptions written, I'm not suggesting that
25 because more than half of prescriptions are

1 written for acute pain that acute -- that more
2 than half of prescriptions were appropriate
3 because -- just because the patient has acute pain
4 doesn't mean they should have an opioid, doesn't
5 mean people should be sent home from hospitals or
6 minor procedures with acute pain with opioids.

7 Q. But that judgment would be made in an
8 individual case by a doctor who would decide what
9 to write as a prescription for acute pain, right?

10 A. Not necessarily. So, I mean -- the
11 doctor -- just because a doctor made the decision
12 doesn't mean that the prescription was
13 appropriate. We are in a situation where we have
14 a medical community that was misinformed about the
15 risks and benefits. So just because -- a doctor
16 may have believed that this was the right thing to
17 do for their patient, but that doesn't mean it was
18 appropriate.

19 Q. Now, I understand the point you're --
20 the distinction you're drawing, but what I wanted
21 to focus on in particular was if a doctor is
22 writing a prescription for acute pain, that's a
23 category that you see as legitimate? The
24 individual prescriptions you might --

25 MR. MAJESTRO: Hey Tim --

1 MR. HESTER: Yes?

2 MR. MAJESTRO: Erin got kicked off,
3 so let's wait a minute for her to get back
4 on.

5 MR. HESTER: Okay. I.

6 MR. MAJESTRO: Got kicked off too,
7 but I'm obviously back on.

8 THE VIDEOGRAPHER: Would you like to
9 temporarily go off the record?

10 MR. HESTER: Sure. Sure.

11 Have you done these video depositions
12 before, Dr. Kolodny?

13 THE WITNESS: Just one.

14 THE VIDEOGRAPHER: The time is 9:28
15 and we're off the record.

16 (Recess taken)

17 THE VIDEOGRAPHER: The time is 9:32.

18 We are back on the record.

19 Q. Dr. Kolodny, before the break, we
20 were talking about the share of prescriptions that
21 are written for acute pain circumstances and I
22 understand your point to be that in your view, not
23 all such prescriptions are appropriate for acute
24 pain, right?

25 A. I would say that many -- maybe

1 most -- acute pain prescriptions aren't necessary.
2 So then if you, for example, compare opioid
3 prescribing in the United States to other
4 countries with really good health care systems,
5 like in western Europe, opioids are not really
6 used outpatient for acute pain. Patients aren't
7 sent home from the hospital with acute pain
8 prescriptions.

9 Q. But I wanted to ask you a slightly
10 different question, which is a doctor who writes a
11 prescription for acute pain is making a judgment
12 that the prescription is appropriate for that
13 circumstance, correct?

14 A. That's correct.

15 Q. Okay.

16 And we talked before about the share
17 of prescriptions that are written for acute pain
18 and I believe you said that you understood it was
19 greater than 50%, although you didn't have the
20 specific number in your head, right?

21 A. Correct.

22 Q. Do you know what share of
23 prescriptions in West Virginia are written for
24 acute pain?

25 A. I don't know if I've seen data on

1 that. No, I don't believe I can answer that
2 question.

3 Q. You've not seen any data on that?

4 A. I don't believe I've seen data on
5 opioid prescribing and the diagnosis of the
6 patients receiving the opioid prescription in the
7 State of West Virginia.

8 Q. Do you have any reason to believe
9 that the share of prescriptions written for cancer
10 pain would be higher in West Virginia?

11 A. I believe because -- I don't think
12 West Virginia could be that different from the
13 rest of the United States, so I believe that
14 prescriptions written for cancer in the State of
15 West Virginia constitute a small percentage of
16 opioid prescriptions.

17 Q. Do you know the percentage?

18 A. I have not seen that data, I don't
19 believe.

20 (Whereupon, Exhibit 4 was marked for
21 identification.)

22 Q. Let me ask you if you could open up
23 Exhibit 4, please.

24 Do you have it there?

25 A. I do.

1 Q. So Exhibit 4, which we premarked, is
2 written by Nora Volkow entitled "Opioid Abuse in
3 Chronic Pain - Misconceptions and Mitigation
4 Strategies."

5 Do you see that, Dr. Kolodny?

6 A. I do.

7 Q. And this is a document that you cite
8 in your report; is that right?

9 A. I believe I do.

10 Q. Yes. If you need to confirm, I know
11 it's cited in your report in note 17, page ten.

12 A. Okay.

13 Q. You're familiar with this document?

14 A. I am familiar with this paper.

15 Q. Okay. And let me ask you to look at
16 the first page. It's 1253.

17 Do you see under the heading "Source
18 of the Opioid Epidemic," there's a first sentence
19 that reads "More than 30% of Americans have some
20 form of acute or chronic pain"?

21 Do you see that?

22 A. Yes.

23 Q. Is that a statement you agree with?

24 A. I would like to look at what they're
25 citing for that, but as I mentioned before, part

1 of feeling pain -- you know, part of being alive
2 involves feeling pain. So many Americans very
3 frequently and many humans very frequently feel
4 pain. That's not necessarily an indication that
5 30% of Americans need opioids or even need a pill
6 for their pain of any sort.

7 Q. That wasn't what I asked you, though.
8 I just asked whether you agree with
9 this statement: "More than 30% of Americans have
10 some form of acute or chronic pain."

11 A. I'm not sure. I want to look at the
12 studies and many of the studies on that topic have
13 been influenced by the opioid industry, including
14 opioid distributors, so I globally look closely at
15 what was being cited there.

16 Q. I really need you to answer my
17 questions, though. That was a narrow question.
18 Do you agree with this statement --
19 do you agree with this statement: "More than 30%
20 of Americans have some sort of acute or chronic
21 pain"?

22 If you do or don't, you can say yes
23 or no.

24 MS. DICKINSON: Objection to form.
25 Argumentative.

1 He's answered the question two or
2 three times. He's going to answer it with
3 completeness in the way that he needs to to
4 be accurate.

5 Go ahead, Doctor, if you want to
6 answer again.

7 A. It's not a yes or no question. I
8 can't really answer whether I agree with it or
9 disagree with it without looking at who they
10 cited.

11 Q. Okay.

12 Do you know what the numbers are on
13 the percentage of Americans who have acute or
14 chronic pain?

15 A. I have seen estimates all over the
16 place and many of the studies on this topic are
17 not reliable because they've been influenced by
18 the opioid industry.

19 Q. Do you see the next sentence: "Among
20 older adults the prevalence of chronic pain is
21 more than 40%"?

22 Do you agree with that statement?

23 A. I don't agree or disagree with it. I
24 really want to look at the support for that
25 statement.

1 Q. Do you know the statistics in West
2 Virginia for the prevalence of chronic pain among
3 older adults?

4 A. I do not --

5 MS. DICKINSON: Objection to form.

6 A. -- know what percentage of people in
7 West Virginia -- older adults -- have chronic pain
8 and I would be suspicious of any study that claims
9 to have that data. That's something that's very
10 difficult to assess.

11 Q. Let me ask you to look further down
12 in the page. Do you see at the end of the first
13 paragraph that we've just been looking at, there's
14 a sentence that reads "Although opioid analgesics
15 rapidly relieve many types of acute pain and
16 improve function" -- I want to focus on that
17 phrase.

18 Do you see that phrase?

19 A. Yes.

20 Q. Do you agree with that?

21 MS. DICKINSON: Objection to form and
22 misstates the document in terms of it's only
23 half of the sentence you're reading from.

24 MR. HESTER: I think that's a
25 speaking objection, Erin. You can object to

1 the form. I'm asking Dr. Kolodny about
2 one-half of the sentence.

3 Q. I understand there's a second half of
4 the sentence, Dr. Kolodny, but the first half is
5 what I wanted to ask you about.

6 A. I can't really agree or disagree with
7 it. I think the authors might have gotten a
8 little ahead of the evidence on that because I'm
9 not aware of studies on opioid use and function
10 for acute pain. I'm aware of studies on opioid
11 use and function for chronic pain, which have
12 shown that they really don't improve function, but
13 I'm not aware of studies -- so I think it's
14 possible that the authors may have gotten a little
15 ahead of the data on this.

16 Q. Have you seen studies that are
17 contrary to this point, the point being that
18 opioid analgesics rapidly relieve many types of
19 acute pain and improve function?

20 A. So it is -- opioids are effective for
21 acute pain and there are many studies that show
22 that. I'm not aware of studies that show that
23 opioids improve function in people with acute pain
24 because function is generally a concern in people
25 with chronic pain, not acute pain. We don't

1 really think about function in somebody who just
2 had surgery.

3 (Whereupon, Exhibit 5 was marked for
4 identification.)

5 Q. Let me ask you to look, please, at
6 Exhibit 5. I may come back to some of these, so
7 you can keep a stack of them, but the new one to
8 open is Exhibit 5.

9 A. I have it.

10 Q. Exhibit 5, which we premarked, is
11 written by Bruce Naliboff and others and it's
12 entitled "A Randomized Trial of Two Prescription
13 Strategies for Opioid Treatment of Chronic
14 Nonmalignant Pain."

15 Do you see that?

16 A. I do.

17 Q. Is this a document you've seen
18 before?

19 A. I'm not -- I'm not certain.

20 Q. It's cited -- it's cited in your
21 report. I don't mean to make this a memory
22 contest. It is cited in your report at note 12.

23 A. Okay.

24 Q. So do you see -- let me ask you to
25 look at page 288, which is the first page, and I

1 want to direct you to the right-hand column.
2 There's a reference to -- in the first sentence on
3 that right-hand column, there's a reference to a
4 study by Kalso, et al, concluded that opioids led
5 to a consistent reduction of at least 30% in pain
6 severity in short-term trials.

7 Do you see that?

8 A. Yes, I see that.

9 Q. Is that consistent with your
10 understanding of the data on reductions in pain
11 severity in short-term trials of prescription
12 opioids?

13 A. Yes. Opioids can be effective on a
14 short-term basis.

15 Q. Let me ask you to look back at the
16 CDC guidelines, please, which is Exhibit 3. It
17 should be in your stack. Happily, you don't have
18 to open this one. You already have it.

19 A. I have it.

20 Q. Do you see in the second package --
21 let me point you to page two of the CDC
22 guidelines, Exhibit 3.

23 There's a sentence in the left-hand
24 column, about three or four sentences down,
25 there's a sentence that reads "Evidence supports

1 short-term efficacy of opioids for reducing pain
2 and improving function in non-cancer, no
3 susceptible and neuropathic pain in randomized
4 clinical trials lasting primarily less than 12
5 weeks."

6 Do you see that?

7 A. I do.

8 Q. You don't see that?

9 A. I said I do see that.

10 Q. Okay.

11 Is that consistent with your
12 understanding of the science?

13 A. It's my --

14 MS. DICKINSON: Objection to form.

15 A. It's my -- consistent with my
16 understanding of the published studies on this
17 topic. Most of these short-term trials were
18 studies done by drug companies to have opioids
19 approved and they were short-term trials in people
20 with chronic pain and in those short-term trials,
21 some of those studies showed benefit. There are
22 problems with the methodology used in some of
23 those studies, so I don't know that I'd say that
24 it's consistent with the science. I'd say it's
25 consistent with the published literature on the

1 topic, which is what the CDC is citing.

2 Q. Okay.

3 Have you seen published literature
4 that contradicts this point?

5 MS. DICKINSON: Objection to form.

6 A. I've seen -- yes, I have seen some
7 data that would contradict this finding. I've
8 seen, for example, evidence of clinical trials
9 that were short term for patients with chronic
10 pain that really didn't show much improvement at
11 all.

12 But in general, I think the --
13 there's clearer science that shows that when you
14 take an opioid acutely, even for a chronic pain
15 problem, the opioid works. The problem is when
16 you're taking consistently -- and even for 12
17 weeks, if you're taking consistently for 12 weeks,
18 there are studies that would contradict, there's
19 evidence that contradicts that finding. But
20 almost -- most of what's been published on this is
21 part of clinical trials used for drug approval and
22 that's what the CDC is reporting on.

23 Q. So they're reporting that in general
24 the studies reflect benefits in these shorter term
25 trials?

1 MS. DICKINSON: Objection to form.

2 A. They're trying to indicate what the
3 published literature shows on this subject and
4 that's what they found.

5 Q. And you would consider this an
6 accurate characterization of what the published
7 literature is?

8 A. Yes, I do.

9 Q. Okay.

10 Dr. Kolodny, let me ask you to look
11 at page 68 of your report, please.

12 Do you have it there?

13 A. Yes.

14 Q. Do you see the -- it's the first full
15 paragraph on that page and you say "Since 2008,
16 the public health crisis precipitated by
17 prescription opioids was summarized in numerous
18 news articles, books and media stories and
19 governmental bodies and task force groups have
20 reported on these issues."

21 Do you see that?

22 A. I do.

23 Q. What I wanted to ask you is do you
24 believe today that the medical community has
25 become broadly aware of the risks and benefits

1 associated with longer term use of prescription
2 opioids?

3 MS. DICKINSON: Objection to form.

4 A. That's a good question. I think that
5 the medical community is much more aware today
6 that we have an opioid crisis. I think that --
7 and many of the medical community have
8 increasingly recognized that a lot of what we
9 learned was incorrect.

10 But I'd say that the evidence
11 suggests we have a very long way to go because we
12 still prescribe opioids much more aggressively in
13 the United States than in other countries, which
14 suggests that many clinicians are still not
15 accurately weighing the risks versus the benefits.

16 Q. The clinicians are engaged in that
17 process of weighing risks and benefits? You would
18 agree with that? That's what the clinicians do?

19 A. A clinician is supposed to weigh the
20 risks versus benefits for any treatment for any
21 patient.

22 Q. And clinicians have become more
23 broadly aware in recent years of the risks
24 associated with long term use of opioids; is that
25 right?

1 A. The trends suggest that the medical
2 community is starting to get it. They're starting
3 to better weigh risks versus benefits, but that we
4 have a very long way to go.

5 Q. Let me ask you to look back at the
6 CDC guidance again, Exhibit 3. Let me ask you to
7 look at page three of this document and I wanted
8 to point you to the bottom of the left-hand column
9 over to the top of the right-hand column. It's
10 the last sentence on the left-hand column.

11 It says "Although the transition from
12 use of opioid therapy for acute pain to use for
13 chronic pain is harder to predict and identify,
14 the guideline is intended to inform clinicians who
15 are considering prescribing opioid pain medication
16 for painful conditions that can or have become
17 chronic."

18 Do you see that?

19 A. Yes.

20 Q. You're aware that was one purpose of
21 these guidelines was to give clinicians this
22 information on the risks associated with longer
23 term use of opioids as compared to the benefits?

24 MS. DICKINSON: Objection to form.

25 Foundation.

1 A. I believe that the CDC drafted these
2 guidelines because of concern that there was a
3 massive overprescribing of opioids for chronic
4 pain and they wanted to try and address that
5 problem by providing better information about
6 risks, but also by communicating to the medical
7 community that evidence of effectiveness is
8 lacking.

9 Q. And yet you're also aware that
10 doctors continue to prescribe opioids at certain
11 levels for a number of purposes, right?

12 A. I'm aware that doctors, especially in
13 the United States, continue to prescribe a lot of
14 opioids.

15 Q. And so doctors are making individual
16 judgments about the benefit and the risk, correct?

17 A. That's correct. For -- and not just
18 doctors, but any health care professional, any
19 clinician is supposed to weigh risks versus
20 benefits for any treatment. The problem with
21 opioids is that to this day, many are not weighing
22 risks versus benefits well because they were
23 misinformed and if you underestimate the risks
24 and/or overestimate the benefit of any treatment,
25 you may be likely to inappropriately prescribe

1 that treatment.

2 Q. And over the last ten years, there's
3 been much more focus on risks associated with
4 opioids and much broader dissemination of
5 knowledge about risks associated with opioids; is
6 that right?

7 MS. DICKINSON: Objection to form.

8 A. I would say there's over -- I would
9 say maybe since around 2010, 2011 is when we
10 started to see an effort made to communicate to
11 the medical community that risks had been
12 inappropriately minimized and the benefits have
13 been exaggerated and that effort to get the word
14 out to the medical community has had a positive
15 impact, but we have a very long way to go.

16 Q. But the medical community today is
17 still making a judgment about prescribing opioids
18 based on the weighing of risks and benefits based
19 on the further knowledge that's been disseminated,
20 right?

21 MS. DICKINSON: Objection to form.

22 Foundation.

23 A. For any treatment prescribed by any
24 clinician, you weigh -- the clinician is supposed
25 to weigh the risk versus benefits for the patient

1 in front of them, whether it's opioids or whether
2 it's surgery.

3 (Whereupon, Exhibit 9 was marked for
4 identification.)

5 Q. Let me ask you to look at Exhibit 9,
6 please.

7 Do you have that one there, Dr.
8 Kolodny?

9 A. I do.

10 Q. Exhibit 9, which we premarked, is by
11 Mark Edlund and others entitled "The Role of
12 Opioid Prescription in Incident Opioid Abuse and
13 Dependence Amongst Individuals with Chronic
14 Noncancer Pain."

15 Have you seen this document before?

16 A. I have.

17 Q. This is cited in your report, right?

18 A. It is.

19 Q. Let me ask you to look at the first
20 page of the document please, 557.

21 A. Yes.

22 Q. Do you see in the -- let me point you
23 to the right-hand column -- the first full
24 paragraph in the right-hand column, the last few
25 sentences. There's a sentence that begins "A key

1 clinical issue facing clinicians is how to balance
2 the potential benefits of opioid therapy with
3 risks of addiction in CNCP patients for who
4 they're contemplating initiating opioid therapy."

5 Do you see that?

6 A. I'm sorry. Which paragraph are you
7 reading from?

8 Q. It's the first full paragraph on the
9 right-hand side.

10 A. Yes.

11 Q. Sorry. This remote work is a little
12 harder to point you to pieces of the document, but
13 it's the right-hand side, the first full
14 paragraph.

15 A. I do see that, yes.

16 Q. And the sentence I wanted to point
17 you to is "A key clinical issue facing clinicians
18 is how to balance the potential benefits of opioid
19 therapy with risks of addiction in CNCP patients
20 for whom they're contemplating initiating opioid
21 therapy."

22 Do you see that?

23 A. I do.

24 Q. And CNCP refers to chronic non-cancer
25 pain, right?

1 A. Yes, it does.

2 Q. And do you agree with the statement
3 there?

4 MS. DICKINSON: Objection to form.

5 A. Yes.

6 Q. Let me ask you to look at the next
7 sentence where it says "The clinical importance of
8 this issue is heightened by the fact that in some
9 patients, opioids are the only viable option for
10 managing their pain."

11 Do you see that?

12 A. Yes.

13 Q. Do you agree that for some patients,
14 opioids are the only viable option for managing
15 pain?

16 MS. DICKINSON: Objection to form.

17 A. Yes. Palliative care would be a good
18 example.

19 Q. Here, he's talking about chronic
20 non-cancer pain.

21 Do you agree that for some patients,
22 opioids are the only viable option for managing
23 chronic non-cancer pain?

24 MS. DICKINSON: Objection to form.

25 Foundation.

1 A. It's a good question. I'd have to
2 really think that through. I think -- you know,
3 it's possible there are patients with pain that's
4 chronic and so severe that you're basically going
5 to give them massive amounts of opioids and
6 probably other drugs so as to put them almost into
7 a narcotic stupor because there's nothing else you
8 can do for them, but -- you know, I think that
9 that would be uncommon. It's a good question.
10 I'd have to think about it a bit more. I wasn't
11 really asked to opine on that specifically.

12 Q. Do you disagree with what Dr. Edlund
13 writes here?

14 MS. DICKINSON: Objection to form.

15 A. If Dr. Edlund had written that for
16 some people with low back pain, opioids are the
17 only thing that can give them relief, I would
18 disagree. He didn't write that and so what he
19 wrote here is vague and difficult for me to say
20 whether I agree with it or not.

21 Q. Let me ask you to turn to page eight
22 of your report, please. I wanted to ask you about
23 a sentence on the very top of page eight. It's
24 the second full sentence on the page: "Studies
25 have found that many patients on long-term opioids

1 for chronic pain meet criteria for DSM-V" -- or 5
2 -- "Opioid Use Disorder."

3 Do you see that?

4 A. I do.

5 Q. How many? When you use the word
6 "many" in that sentence, do you have in mind a
7 number?

8 A. Yes. I believe in that study when
9 you included mild Opioid Use Disorder, it was more
10 than a third of patients that met criteria for
11 Opioid Use Disorder using DSM-5 criteria.

12 I think for DSM-IV criteria where the
13 term "dependence" is used to mean addiction rather
14 than Opioid Use Disorder, they found about 25% met
15 criteria for addiction and so that -- that's a
16 very high prevalence.

17 Q. But I guess flipping it around the
18 other way then, if I understood what you just
19 said, Dr. Kolodny, that would mean about
20 two-thirds of the patients on long-term opioids
21 for chronic pain would not meet the criteria for
22 OUD?

23 MS. DICKINSON: Objection to form.

24 A. I don't know if I would say that it
25 means two-thirds don't meet criteria. It would

1 mean that in this particular study that two-thirds
2 of the patients that were assessed didn't give --
3 the folks doing the study didn't acknowledge
4 evidence of addiction and studies like this are
5 very difficult to do because if somebody has
6 Opioid Use Disorder and they're participating in a
7 study and they indicate to the people performing
8 the study that they meet criteria, they're at risk
9 of being cut off from their opioid supply and for
10 people that are addicted, that's a very
11 frightening prospect. It means they might have to
12 line up at a methadone clinic, it means they might
13 wind up buying drugs on the street.

14 So all of these studies are difficult
15 to perform. What they found was that a third did
16 report -- did indicate criteria that indicated
17 Opioid Use Disorder or addiction. That doesn't
18 mean that the two-thirds didn't have the
19 condition.

20 Q. No, but in terms of the study,
21 two-thirds did not end up reporting
22 characteristics that led to the conclusion that
23 they met the criteria, right?

24 A. That's correct.

25 Q. The other number you reference, which

1 is the DSM-IV standards, I believe you said 25%
2 met the DSM-IV standards for OUD?

3 A. I believe in the study by Boscarino
4 that was cited here, I believe they found 25% met
5 criteria for Opioid Use Disorder. That is
6 correct.

7 Q. So again, they found that 75% in that
8 study did not mean that criteria?

9 MS. DICKINSON: Objection to form.

10 A. No, they didn't find that 75% didn't
11 meet criteria. They only had 25% that reported
12 the criteria.

13 Q. I understand.

14 But that would also mean that they
15 didn't find, from among that population they were
16 looking at, there were 75% of the population they
17 looked that that did not meet the criteria as they
18 were measuring it?

19 MS. DICKINSON: Objection to form.

20 A. Twenty-five percent of the patients
21 provided evidence that they have DSM-IV opioid
22 dependence. That evidence wasn't elicited from
23 75% of the people that they surveyed.

24 Q. The sentence that we were just
25 looking at refers to patients on long-term

1 opioids.

2 Do you see that in your report?

3 A. Yes.

4 Q. What does long term mean there?

5 A. In general, long-term opioid therapy,
6 that term is used interchangeably with chronic
7 opioid therapy and most studies usually use 90
8 days of continuous use as the marker.

9 Q. So most studies would view use of 90
10 days or less as short term or acute use versus
11 chronic use?

12 A. Much of what's in the literature uses
13 90 days or more as the -- as a cut off for --
14 really, for defining chronic opioid therapy
15 or long-term opioid therapy, but much of the more
16 recent literature would really define long term as
17 even more than seven days after acute pain.

18 Q. You think there's literature that
19 defines use of opioids for more than seven days as
20 long term?

21 A. Well, I think -- I don't know. Yes,
22 I think there's literature right now that would
23 define more than seven days as being long and
24 inappropriate for acute pain.

25 Q. Now, what I'm trying to get to is the

1 phraseology you're using of "long term."

2 When you used it in your report.
3 Were you referring to use for more than 90 days?

4 A. I think that I'd have to look at the
5 specific use in my report. I think in many cases
6 where I used the term "long-term opioid therapy,"
7 especially if I'm referring to what's in the
8 literature, I'm using the term interchangeably
9 with "chronic opioid therapy." Those studies
10 generally are for people on opioids 90 days or
11 more.

12 Q. Do you know what percentage of
13 prescriptions are written for shorter-term
14 therapy, less than 90 days?

15 A. The majority of prescriptions -- as I
16 mentioned earlier, most prescriptions that are
17 written, more than half -- and maybe even
18 significantly more than that -- are written for
19 acute pain and typically, they -- it's a pill
20 bottle that has 20 pills of five-milligram
21 Hydrocodone. So if you're talking about the share
22 of prescribing in terms of numbers of
23 prescriptions written, acute pain is a large piece
24 of it.

25 If you're talking about consumption

1 of opioids in morphine equivalence, chronic opioid
2 therapy, chronic non-cancer pain is a -- probably
3 a very large percentage of the overall
4 consumption.

5 Q. I really wanted to focus on number of
6 prescriptions in my question here.

7 So in terms of number prescriptions,
8 well more than half of the total prescriptions for
9 opioids would be for less than 90 days?

10 MS. DICKINSON: Objection.

11 Form.

12 A. Well, a prescription can only be
13 written for 30 days. So if you are getting
14 repeated prescriptions every 30 days, once you've
15 done that for more than three months, we start to
16 define the treatment you're getting as -- as
17 chronic opioid therapy.

18 It's difficult, though, to really
19 answer your question because there are also
20 studies showing us that patients who wind up on
21 chronic opioid therapy overwhelmingly began their
22 opioid career with an acute pain prescription and
23 never got off.

24 MS. DICKINSON: Tim, could I ask
25 just -- I don't want to interrupt this line

1 of questions, but when you get to a breaking
2 place, can we take a break? It's been a -- I
3 know we hopped off because of technical
4 difficulties, but it's been about an hour and
5 ten minutes and we just need a five- or
6 ten-minute break.

7 MR. HESTER: Yeah. I could stop now
8 if you want me to. Do you want to stop now
9 or should we go a little longer?

10 MS. DICKINSON: It's totally up to
11 you. If you've got, you know, three minutes
12 in this line of questions, certainly go
13 ahead. I don't want to break up your flow.
14 But I do think that we're probably -- we've
15 gone over an hour. I'd kind of like to take
16 just a short one if we can when if you're at
17 a stopping point.

18 MR. HESTER: We can take a break now.

19 MS. DICKINSON: Okay.

20 MR. HESTER: How should we work the
21 mechanics? We're not all in the same place,
22 we don't know when we're coming back. Should
23 we come back around 10:15?

24 MS. DICKINSON: Yes. It's 9:09 here,
25 10:09 there. Let's just make sure we're all

1 back in the room roughly around 10:15 and as
2 soon as we see you, me and Dr. Kolodny. We
3 certainly could start.

4 MR. HESTER: Okay. Thanks.

5 MS. DICKINSON: Dr. Kolodny, is that
6 okay with you? Do you need a longer break
7 than that?

8 THE WITNESS: Sounds good. We're
9 going to tune back in at what time?

10 MS. DICKINSON: In five minutes at
11 10:15 your time.

12 MR. HESTER: Is that okay?

13 THE WITNESS: Yes, sounds great.

14 THE VIDEOGRAPHER: The time is 10:10
15 and we're now off the record.

16 (Recess taken)

17 THE VIDEOGRAPHER: The time is 10:18
18 and now we are back on the record.

19 Q. Dr. Kolodny, before the break, I was
20 asking you about this statement in your report
21 about patients on long-term opioids for chronic
22 pain and I was trying to understand your view on
23 the percentage of prescriptions written for
24 patients on long-term opioids as compared to the
25 percentage of prescriptions written for patients

1 who are using opioids on a shorter term basis,
2 less than 90 days.

3 MS. DICKINSON: Objection to form.

4 A. It's a difficult question to answer.
5 Evidence -- national data on prescribing suggests
6 that a large majority of prescriptions have -- are
7 meant for less than a month and have less than a
8 month's worth of pills in them.

9 West Virginia, though, may be unique.
10 Some of the data that I reviewed showed a massive
11 amount of Oxycodone 30 milligrams that were
12 dispensed or even Oxycodone 15 milligrams. Those
13 pills are very high dosage and generally would not
14 be given to someone who didn't already have a
15 tolerance to opioids. So sometimes by looking at
16 the dose, you can get a sense that maybe this was
17 for someone who was on opioids long term.

18 Q. Those doses can also be used for
19 someone who is at end of life or has cancer pain,
20 correct?

21 A. Correct. A 30-milligram Oxycodone is
22 equal to about nine five-milligram Vicodin in one
23 pill. Imagine nine Vicodin in a single pill.
24 Most people who would take that who don't have an
25 opioid tolerance would get very sick and maybe it

1 could be potentially even be fatal, just one pill.
2 So those should only be for people who have built
3 up quite a tolerance to opioids.

4 Q. Or who are in acute pain or cancer
5 pain?

6 A. Anyone who has built up a tolerance
7 to opioids, whether it's cancer pain, whether it's
8 addiction. Someone who is tolerant to opioids.

9 And I believe for some of the data I
10 reviewed, there were pharmacies in West Virginia,
11 in Cabell County and Huntington, where it looked
12 like a very large percentage of the pills that
13 were sold to these pharmacies were for these very
14 high-strength dosages.

15 Q. What studies are you referring to?
16 What data are you referring to?

17 A. I'm referring to data I believe from
18 the expert report of Craig McCann. *

19 Q. Have you done any independent looking
20 or is it based on the report from Mr. McCann?

21 A. This has his analysis.

22 Q. Okay. Let me ask you to look at your
23 report, page nine.

24 In the second full paragraph, there's
25 a sentence that says "The bulk of opioid

1 consumption in the US is for common chronic
2 conditions."

3 Do you see that?

4 A. Yes, I do.

5 Q. And when you say bulk, what do you
6 mean there? Do you mean number of prescriptions
7 or do you mean MME?

8 A. Well, I think the most accurate way
9 to measure opioid consumption is not by counting
10 the number of prescriptions. I think that can be
11 very misleading. That's typically how the opioid
12 industry likes to measure consumption. I'm
13 talking about weight of opioids consumed and yes,
14 MME is a way of standardizing opioids of different
15 potency. So when you measure the amount of
16 opioids consumed in terms of weight and kilograms,
17 the consumption -- the bulk of that consumption --
18 and by bulk is not really a scientific term; I
19 guess I could have been more precise -- but I
20 believe more than half of that weight of opioid
21 consumed is for conditions where opioids are
22 probably not appropriate.

23 Q. I wanted to ask you about a different
24 question, though.

25 In terms of the number of

1 prescriptions, I take it that the point is
2 different from the point you make there. In terms
3 of number of prescriptions, the bulk of
4 prescriptions written would not be for common
5 chronic conditions; is that right?

6 MS. DICKINSON: Objection to form.

7 A. Yes. I would say that more than half
8 of the prescriptions are not for chronic pain.
9 They may still be inappropriate, though, because
10 we are still overprescribing for acute pain. But
11 yes, to answer your question, I believe if you
12 were measuring consumption in terms of numbers of
13 prescriptions written, which I don't think is a
14 good way to measure consumption, yes, more than
15 half would be probably be for acute pain.

16 Q. And when you say here that the bulk
17 of opioid consumption is for common chronic
18 conditions -- and I understand you're referring to
19 weight or MME -- what's the basis for your
20 statement?

21 A. Data that I've reviewed on opioid
22 consumption in the United States using MME.

23 Q. Did those data tie to particular
24 uses?

25 MS. DICKINSON: Objection to form.

1 A. Yes. These were studies done where
2 it used the indication of -- the patient's
3 diagnosis was used.

4 Q. Do you have any particular studies in
5 mind?

6 A. I've got a slide that I could think
7 of that I've shown, but I can't remember in that
8 slide who I cited. So I'd have to really go back
9 and look for that. But it's -- you don't
10 necessarily need a study to show you that
11 consumption for chronic pain by weight is going to
12 be a pretty huge number because if you look at the
13 average prescription that's written for acute
14 pain, there might be 10 five-milligram pills in
15 it, so the total weight might be 50 MME, whereas
16 if you were to look at an oxycodone 30-milligram
17 prescription that -- especially some of the
18 prescriptions that were likely dispensed in West
19 Virginia -- each pill could be for 30 milligrams,
20 so each pill would be similar to nine Vicodin and
21 I have 240 of those pills in the container, so
22 it's just a lot heavier. It's apples and oranges.

23 Q. Let me ask you where you're talking
24 here about the bulk of opioid consumption for
25 common chronic conditions. I wanted to understand

1 whether you're talking about chronic use of
2 opioids or chronic conditions that might be
3 treated in a short-term basis.

4 A. When I say common chronic conditions,
5 I'm referring to -- generally to low back pain
6 with a normal spine, also called neurostructural
7 low back pain or axial low back pain. I'm
8 referring to fibromyalgia and I'm referring to
9 headache, chronic headache conditions. Those are
10 generally what comes to my mind when I write
11 chronic conditions with regard to opioids, those
12 three.

13 Q. And do you agree that some of those
14 chronic conditions might be treated with a
15 short-term burst of opioids?

16 MS. DICKINSON: Objection to form.

17 A. Not really. There are chronic
18 conditions where intermittent use of an opioid
19 would be appropriate, like rheumatoid arthritis or
20 gout where the person who is taking the opioid on
21 an intermittent basis really for an acute flare up
22 of a chronic condition, so that could be
23 appropriate. But low back pain with a normal
24 spine, fibromyalgia and chronic headache are
25 conditions where opioids really shouldn't be used.

1 Q. When you say the intermittent use for
2 a chronic condition could be appropriate, what's
3 the reason for that?

4 A. The opioids, when you take them
5 intermittently, they provide pain relief. When
6 you take an opioid every day for weeks and months
7 and years, the opioid will no longer continue to
8 provide pain relief unless the dose keeps going
9 higher because of tolerance. So tolerance sets in
10 rapidly when you're taking the opioid every day.

11 And so as the -- say you have to keep
12 increasing the dose and as the doses get higher,
13 you'll generally see that the patient's level of
14 function starts to decline. The patient becomes
15 more sedated and of course as the dose gets
16 higher, the patient is more likely to experience
17 side effects, including addiction and overdose.

18 Q. You would distinguish between that
19 sort of steady use and an intermittent use of an
20 opioid for a chronic condition?

21 A. That's correct. If you take an
22 opioid intermittently, for example, the patient
23 who takes a five-milligram Vicodin a couple times
24 a month on a really bad day, that can be an
25 effective strategy for using an opioid in a

1 patient who may not be able to tolerate other pain
2 treatments. But when they are taking it every day
3 around the clock, that's generally a recipe for
4 disaster.

5 Q. Let me ask you to look back at
6 Exhibit 4, which is the Volkow paper.

7 Do you have that there?

8 A. Yes.

9 Q. Do you see in the first full
10 paragraph under the heading she's got a statement
11 that says "In 2014 alone, US retail pharmacies
12 dispensed 245 million prescriptions" and then she
13 says "Of these prescriptions, 65% were for
14 short-term therapy, less than three weeks."

15 Do you see that?

16 A. Yes.

17 Q. Is that consistent with your
18 understanding of what the data shows?

19 A. As I mentioned, I thought it was more
20 than half. I think that's probably accurate.
21 Sixty-five percent for short term makes sense to
22 me.

23 Q. Let me ask you to look at Exhibit 9,
24 please. This is the Edlund study. I wanted to
25 point you to page 562. It's in the left-hand

1 column on page 562, the last paragraph.

2 It's the third sentence that begins
3 with however and it says "Among the 35% who
4 received opioids, only 5% proceeded to chronic
5 use" --

6 A. Yes.

7 Q. -- "and only 3% of these proceeded to
8 chronic use of high daily doses."

9 Do you see that?

10 A. Yes.

11 Q. Is that consistent with your
12 understanding of the science?

13 MS. DICKINSON: Objection to form.
14 Foundation.

15 A. To really understand what they're
16 referring to here -- I know this study well, but I
17 do need just a moment to read the preceding
18 paragraph or two, if that's okay.

19 Q. Sure.

20 A. Okay.

21 Q. So maybe to set the table a little
22 bit on this study, this was a study of patients
23 with chronic non-cancer pain?

24 A. I believe this was a study of
25 patients exposed to opioids. I don't --

1 Q. And it was individuals with new
2 onsets of chronic non-cancer pain?

3 MS. DICKINSON: Objection.
4 Form.
5 Foundation.

6 A. That's correct, yes.

7 Q. In the paragraph we're looking at on
8 562, it says "Among the 35% who received opioids"
9 -- so they're talking about among the 35% who
10 received opioids for new onset of chronic
11 non-cancer pain, right?

12 MS. DICKINSON: Objection.
13 Form.
14 Foundation.

15 A. Correct.

16 Q. Then 5% of those proceeded to chronic
17 use?

18 A. Correct.

19 Q. And only 3% of those proceeded to
20 chronic use of high daily doses, correct?

21 A. Correct.

22 Q. And is that -- have you seen other
23 studies of this same proposition? In other words,
24 chronic non-cancer pain patients who receive
25 opioids and then how many of them progress to

1 longer term therapy and how many progressed to
2 higher doses?

3 MS. DICKINSON: Objection to form.

4 A. I've seen studies showing that about
5 half of patients exposed to an opioid don't like
6 it and stop, so studies where they -- of opioid
7 use for chronic pain where you see about a 50%
8 drop off rate. Early on, patients just do not
9 tolerate being on an opioid. I'm not aware of
10 other studies that found some of the other -- that
11 had some of these other findings which I think are
12 important.

13 Q. And you said you're familiar with
14 this study? You've looked carefully at this one?

15 A. Yes.

16 Q. If you could look back at your report
17 at page nine again, you have a sentence in the
18 second full paragraph where you say "There is not
19 and has never been strong evidence to support the
20 effectiveness of using opioids long term to treat
21 chronic pain."

22 Do you see that?

23 A. I do.

24 MS. DICKINSON: Objection to form.

25 Q. When you say long term there, you're

1 referring to more than 90 days?

2 A. Probably.

3 Q. And do you agree there is evidence
4 for the efficacy of shorter term use of opioids in
5 treating chronic non-cancer pain?

6 MS. DICKINSON: Objection to form.

7 A. It says, as we've discussed, if
8 someone with a chronic pain condition takes an
9 opioid acutely or intermittently, opioids can be
10 effective and there's evidence of that.

11 Q. Let me ask you to look at page ten of
12 your report, please.

13 You say that, at the very top of the
14 page, "Many patients on long term opioids are not
15 doing well."

16 Do you see that?

17 A. I do.

18 Q. Again, when you're using that phrase,
19 long term, you're referring to more than 90 days?

20 A. In this case, yes.

21 Q. When you use the word "many," what
22 percentage do you have in mind?

23 A. I don't think when I used the word
24 "many" I have a percentage in mind. It just means
25 many. It's not -- it's not very precise. I

1 didn't use a statistic. That it's common for
2 patients on long-term opioids to not be doing
3 well. I'd have to take a look at the study here I
4 cited. I know it's reference 15 -- oh, I think I
5 may explain it here.

6 Yeah. So by "many," what I was
7 referring to here is in the next sentence, "A
8 large observational study of long-term opioids
9 found that four out of five chronic pain patients
10 taking opioids continued to experience significant
11 pain and dysfunction."

12 So "many" was referring to four out
13 of five.

14 Q. The incidence of opioid addiction in
15 patients treating with long-term opioids is
16 unknown if they're treated pursuant to doctor's
17 orders, right?

18 MS. DICKINSON: Objection to form.

19 A. To assess the incidence rate, you'd
20 have to perform a study where you took lots of
21 patients who've never had opioids, put them on
22 opioids for 90 days and then assessed how many
23 became addicted and I don't think a prospective
24 study like that has ever been performed.

25 Q. And your report at page 107, I

1 believe, makes this point. If you look at page
2 107, it's the last paragraph on the page, the
3 second sentence where you say "The incidence of
4 iatrogenic opioid addiction in patients treated
5 with long-term opioids is unknown."

6 Do you see that?

7 A. Yes.

8 Q. Again, where you're talking there
9 about long term, you're talking about more than 90
10 days? That's what you mean?

11 A. Yes.

12 Q. Do you agree that there are
13 beneficial uses -- beneficial long-term uses -- of
14 opioids for some patients in pain?

15 MS. DICKINSON: Objection to form.

16 A. So if someone is near the end of life
17 and you have the opportunity to escalate the dose
18 and the increasing side effects and dangerousness
19 as you go higher on the dose because you're in a
20 palliative care setting are less concerning. Yes,
21 there are examples where having someone taking an
22 opioid every day like palliative care, where it
23 can make sense where the benefits might outweigh
24 the risks. So yes, I can think of some
25 circumstances.

1 (Whereupon, Exhibit 2 was marked for
2 identification.)

3 Q. Let me ask you to look at Exhibit 2,
4 please. This is one we'll need to open up.

5 A. I'm sorry. Which one is Exhibit 2?

6 Q. Exhibit 2 --

7 MS. DICKINSON: We haven't yet opened
8 it, Doctor.

9 MR. HESTER: Sorry. That's a new
10 one.

11 Q. Exhibit 2 is a document we marked.
12 That exhibit number is by Dr. Mark Sullivan is
13 entitled "Opioid Therapy for Chronic Pain in the
14 US: Promises and perils."

15 A. Yes.

16 Q. Have you seen this study before?

17 A. Yes.

18 Q. If you could look at page five, the
19 second sentence under the heading on page five
20 where he says "Generally, LtOT is recommended only
21 for patients with intractable pain and no history
22 of substance abuse."

23 Do you see that?

24 A. Yes, I see where it says that.

25 Q. When he uses LtOT, that's an

1 abbreviation for long-term opioid therapy?

2 A. Correct.

3 Q. Do you agree with that statement?

4 MS. DICKINSON: Objection to form.

5 A. The way it's written, it's hard to
6 agree or disagree with it. I think if he wrote
7 that -- he's writing that it -- it's commonly
8 recommended. If he -- if they had written "We are
9 recommending it," I might disagree. It would be
10 tricky because intractable pain is a very vague
11 term, but I think they're saying generally it's
12 recommended. I don't know that they're
13 necessarily saying they agree with that.

14 Q. As I had read this -- and you tell me
15 if this is not the way you understand it -- the
16 point was you would recommend long-term opioid
17 therapy only with a person who has no history of
18 substance abuse and if they have intractable pain.

19 Is that your understanding of what
20 the study is saying?

21 MS. DICKINSON: Objection to form.

22 A. I would probably want to re-read the
23 study. What they're describing here and what the
24 author of this -- the first author on this paper,
25 Mark Sullivan -- one of his contributions to the

1 literature on opioid therapy was his documentation
2 of the adverse selection process. I think that
3 what he's kind of getting at here, which is that
4 if -- what they found is that the patients who are
5 most likely to wind up staying on opioids long
6 term are the patients one would predict would be
7 the worst candidates for long-term opioid therapy,
8 the ones more likely to be at risk for addiction
9 and overdose.

10 So it's really, I think, describing
11 the adverse selection process where the lower-risk
12 patients say I don't really like taking this and
13 are more likely to drop off.

14 Q. And part of his analysis was that
15 longer term users of opioids tended to be people
16 who had a history of substance abuse or other
17 problems that would lead to higher incidence of
18 OUD?

19 MS. DICKINSON: Objection to form.

20 A. Yes, so then he's demonstrated that
21 the patients that are more likely to wind up on
22 long-term opioids are patients with mental health
23 problems and patients with a history of drug or
24 alcohol problems are the ones who are more likely
25 wind up on long-term opioids.

1 Q. Let me ask you to look at page nine
2 of this document, Exhibit 2. Dr. Sullivan's
3 report or study.

4 A. I'm sorry. Page nine of the same
5 document that's in front of me?

6 Q. Yes. Thanks.

7 I wanted to point you to the last
8 sentence or two of the first paragraph under the
9 heading. There's a sentence that reads "There are
10 patients who do well with improved function and
11 quality of life on opioid therapy. These are
12 often older adults with low-dose intermittent
13 use."

14 Do you see that?

15 A. I'm sorry. You were in the middle of
16 the page under the heading?

17 Q. Yes. On page nine, it's the third
18 sentence at the bottom, at the end of that
19 paragraph. It begins "There are patients" -- do
20 you see that?

21 A. Yes.

22 Q. It reads "There are patients who do
23 well with improved function and quality of life on
24 opioid therapy. These are often older adults with
25 low-dose intermittent use."

1 Do you see that?

2 A. I do.

3 Q. Do you agree with that?

4 MS. DICKINSON: Objection to form.

5 A. Let me just take a look at -- I'd
6 really to have to take a look at -- I don't know
7 if I agree with that or not. I'd have to take a
8 look at the reference and much of what's in the
9 literature on this topic is not accurate and so
10 it's possible they were citing an inaccurate
11 paper. I don't know.

12 Q. The literature that is published is
13 often what doctors rely on in making their
14 judgments in particular clinical settings,
15 correct?

16 A. I don't know. It's a good question.
17 I don't -- I don't know if your average practicing
18 clinician is regularly reading medical journals
19 once they're in practice. So I think they're
20 prescribing practices, for example, could be
21 influenced by CME activities, could be influenced
22 by a sales rep, could be influenced by what a
23 pharmacist tells them when they call the pharmacy
24 and say "What do you think about XYZ drug for this
25 patient?"

1 So I think we'd all like to think
2 that all of our doctors are -- spent the weekend
3 with a stack of medical journals, but I doubt that
4 that's really the case.

5 Q. You would also agree that doctors'
6 judgments are influenced by their own experience
7 with their own base of patients, correct?

8 A. Yes, absolutely. Clinical experience
9 influences the way we practice.

10 Q. So doctors gain experience and
11 judgment from treatment patterns they followed
12 with particular patients, correct?

13 A. That's correct, yes.

14 Q. Let me ask you to look back at the
15 Edlund study, Exhibit 9, please.

16 On page 562, the second paragraph, do
17 you see the first sentence of the second paragraph
18 where he says "Our findings have important
19 clinical implications, as they suggest that the
20 risk of an incident OUD is relatively small for an
21 acute trial of opioids."

22 Do you see that?

23 A. No.

24 Q. Do you see that?

25 A. I do.

1 Q. Do you agree with that?

2 MS. DICKINSON: Objection to form.

3 A. I think there's recent evidence
4 that's been published that might call that
5 statement into question. I would say the
6 comparative risk of incident OUD for acute pain
7 versus chronic pain or for an acute trial versus a
8 long-term trial is comparatively low, but we're
9 finding studies that show even with acute pain
10 treatment, high rates -- and some of this, you
11 know, depends on how you -- one would define the
12 risk of OUD, whether it's low or high.

13 So some people might say three
14 people -- 3% of people becoming addicted is high
15 when you think about how severe an addiction is,
16 so it's very difficult to answer that. But more
17 recent trials are -- studies are showing us that
18 even an acute trial of opioids can have a fairly
19 high risk of addiction developing.

20 Q. That risk versus the benefits of
21 treatment, that's something doctors have to gauge?

22 A. Correct.

23 Q. Let me ask you about the next
24 sentence that says "If chronic opioid therapy is
25 being used, low dose poses much less risk of OUDs

1 than medium dose and medium dose is much less
2 risky than high dose."

3 Do you see that?

4 A. Yes.

5 Q. Do you agree with that?

6 A. Yes. So -- when we have no choice
7 but to prescribe an opioid, we should prescribe
8 the lowest possible dose for the shortest duration
9 possible, largely to prevent people from becoming
10 addicted.

11 Q. Do you also agree -- let me point you
12 to the next sentence down where he says "Our data
13 suggests it's almost meaningless to talk of a
14 single rate of OUDs."

15 Do you agree with that?

16 A. I do.

17 MS. DICKINSON: Objection to form.

18 Q. And that's because OUDs are the
19 result of a number of factors including dosage and
20 duration and a number of other issues?

21 A. Mainly dose and duration, yes, so
22 that -- yes, to talk about what percent of people
23 were going to become addicted without taking into
24 consideration duration of use and dose is almost
25 meaningless.

1 Q. Let me ask you to look back at the
2 Volkow study, which is Exhibit 4.

3 A. Yes.

4 Q. Let me ask you to look at page 1256.

5 A. Yes.

6 Q. I wanted to point you to the
7 left-hand column and it's the third sentence down
8 where he says "In contrast, addiction will occur
9 in only a small percentage of patients exposed to
10 opioids."

11 Do you see that?

12 A. Yes.

13 Q. Do you agree with that statement?

14 MS. DICKINSON: Objection to form.

15 A. It depends on how one would define
16 small. If you're talking about a condition as
17 severe as addiction, even a small number could be
18 considered a high risk. For example, if you were
19 talking about a side effect of a medicine causing
20 blindness, if two out of 100 people went blind
21 from a particular medicine, some people might say
22 that's a high risk, some people might say oh, it's
23 only 2%. It's sort of a judgment call.

24 But it is true that a very large
25 percentage of Americans are exposed to opioids in

1 the course of a single year and the number of
2 people who wind up getting addicted is generally
3 pretty low compared to the number of people that
4 are exposed because a lot of people take one
5 opioid and hated it and don't want to take another
6 and much of the prescribing is as we've talked
7 about, a few pills for acute pain where the risk
8 is a lot lower.

9 Q. So here, where he's talking not about
10 risk, but about small percentage, you would agree
11 that addiction will occur in only a small
12 percentage of patients exposed to opioids?

13 MS. DICKINSON: Objection to form.

14 A. It really -- it's hard to answer that
15 question because some people might say that 2% of
16 people developing severe side effect is a high
17 percentage. So it's really difficult to say.

18 Q. Let me ask you to look at the Volkow
19 study, Exhibit 4. Oh, we're on it. Sorry. We're
20 on Exhibit 4.

21 Let me ask you to turn to page
22 1557 --

23 A. If I could correct you, though, this
24 isn't a study. This is an editorial or review
25 article. I don't think they've done any

1 independent -- it's a review of literature. It's
2 not a study that they're reporting on.

3 Q. Fair enough.

4 So in other words, this is a paper
5 that has reviewed other studies and then reports
6 conclusions based on the conglomeration of the
7 studies?

8 MS. DICKINSON: Objection to form.

9 Q. Correct?

10 A. Yes, correct. They're reviewing the
11 literature, not really reporting on a study they
12 performed.

13 Q. And it's published in the New England
14 Journal of Medicine, which is a reputable journal?

15 A. It is.

16 Q. Let me ask you to look at page 1257,
17 please. It's in the left-hand column, the first
18 full paragraph on the left-hand column. I'm about
19 probably eight or nine sentences in.

20 There's a sentence that begins
21 "However, we do know that the risk of opioid
22 addiction varies substantially among persons, that
23 genetic vulnerability accounts for at least 35 to
24 40% of the risk associated with addiction and that
25 adolescents are at increased risk."

1 Do you see that?

2 A. Do you mind if I just read that
3 paragraph?

4 Q. Sure. That's fine.

5 A. Yes.

6 Q. Was your yes that you've seen it now
7 or should I ask you the question?

8 A. Yes, I've seen it now. You can ask
9 me the question.

10 Q. Okay.

11 So there's a sentence that reads "We
12 do know that the risk of opioid addiction varies
13 substantially among persons, that genetic
14 vulnerable accounts for at least 35 to 40% of the
15 risk associated with addiction and that
16 adolescents are at increased risk."

17 Do you see that?

18 MS. DICKINSON: Objection to form.

19 A. Yes.

20 Q. Do you agree with that statement?

21 A. I am familiar with evidence that
22 adolescents are at increased risk. I haven't
23 seen -- I haven't seen the studies that they're
24 citing. I would like to look at them. A lot of
25 what is in the literature about opioids and risk,

1 especially what's in the literature on risk of
2 addiction I know is incorrect and was influenced
3 by defendants in opioid litigation.

4 So I would want to take a look at
5 those studies and make sure that Drs. Volkow and
6 McLellan weren't mislead on that statistic. So I
7 don't know about that 35 to 40% estimate. I do
8 know that adolescents are at high risk for
9 development of addiction when exposed to highly
10 addicted drugs. There are studies that do show us
11 that.

12 Q. Do you understand generally that
13 genetic variability accounts for at least some of
14 the risk associated with addiction arising out of
15 opioids?

16 MS. DICKINSON: Objection to form.

17 A. So genetics play an important role
18 when it comes to addiction to alcohol and the
19 literature there is good. It's not great. We
20 haven't identified the alcohol gene or genes, but
21 we know that alcohol addiction runs in families.

22 When it comes to highly addictive
23 drugs, like nicotine, heroin, methamphetamine,
24 with highly addictive drugs, repeated exposure in
25 almost anyone puts that individual at high risk

1 for becoming addicted.

2 I think the Sullivan paper that we
3 left a moment ago does a nice job of showing that
4 dose and duration may be more significant when it
5 comes to exposure to a highly addictive drug than
6 what was commonly believed, which is that the
7 individual vulnerabilities are what lead to
8 addiction.

9 Q. But I want to ask a narrow question,
10 which is do you understand that genetic
11 variability plays a role in addiction risk
12 associated with opioids?

13 MS. DICKINSON: Objection to form.

14 A. I have not seen studies demonstrating
15 with opioids what they're indicating here, so I'd
16 want to look at those studies before I answer your
17 question. I wasn't really asked to opine on that.

18 Q. Okay.

19 So when you look at this statement
20 referring to risk of opioid addiction varies
21 substantially among persons and the genetic
22 vulnerability accounts for a share of risk
23 associated with addiction, you don't know one way
24 or another on that point?

25 MS. DICKINSON: Objection.

1 Misstates the document.

2 A. I think we just reviewed a study
3 which I think helps debunk the popular narrative
4 that was promoted by the opioid industry that
5 opioids are not inherently addictive or inherently
6 risky, that there are individuals who are
7 vulnerable and that genetics are largely
8 determinative.

9 I think that we've got good evidence
10 to suggest that that estimate there might be an
11 overstatement, but I would like to review a study
12 of their citing before I really give you a firm
13 opinion about whether or not I agree with that
14 estimate.

15 Q. Whether or not you know the specific
16 numbers, have you -- do you have a general
17 understanding that genetic variability has an
18 impact on risk of opioid addiction?

19 MS. DICKINSON: Objection to form.

20 Asked and answered.

21 A. So with highly addictive drugs, dose
22 and duration become much more important than
23 genetic vulnerabilities. I think that genetics
24 can play a role. So, for example, genetics play a
25 role in our personalities and certainly an

1 individual who may be genetically prone to have
2 poor impulse control might be someone more likely
3 to repeat use of a highly addictive drug and
4 therefore become addicted to it.

5 So I do believe that genetics play a
6 role in development of addition to opioids, but
7 with highly addictive drugs, I believe that the
8 inherent effect of the drug on the brain is more
9 important than these genetic differences. It's
10 the repeat use that becomes much more important
11 than genetic vulnerabilities when you talk about a
12 highly addictive drug.

13 If you talk about a less addictive
14 drug like alcohol, that's where genetic
15 differences become more important.

16 Q. Are you aware of studies showing that
17 a history of substance abuse is often associated
18 with opioid addiction?

19 MS. DICKINSON: Objection to form.

20 A. If you abuse -- I mean, there are
21 studies that -- you don't really need a study. If
22 someone abuses opioids, they're going to be at
23 greater risk of becoming addicted to opioids,
24 similar -- opioid addiction generally develops
25 from repeated use. If you're repeating use

1 because it's fun and you like the effect, you're
2 abusing it and you're someone who abuses drugs and
3 takes them for fun, yes, that's going to make you
4 at high risk of becoming addicted.

5 If you're taking opioids repeatedly
6 because the doctor prescribed them, you'll be at
7 high risk for becoming addicted. If you're taking
8 them repeatedly because you're self medicating
9 some dysphoric feelings, you'll be at high risk
10 for becoming addicted.

11 So again, as demonstrated in the
12 Sullivan paper, what I believe is most determinant
13 is duration of use and dose is also very
14 important.

15 Q. I was asking you a slightly different
16 question about substance abuse, though, which is a
17 history of prior substance abuse, are you aware of
18 studies showing that a history of prior substance
19 abuse of other substances is a predictive factor
20 in relation to developing an addiction to opioids?

21 A. I'm aware of published papers with
22 more or less that statement, published papers that
23 discuss risk factors for becoming addicted where a
24 history of substance abuse is considered a risk
25 factor.

1 Q. Okay.

2 Let me ask you to -- we'll switch
3 gears a little bit here. I wanted to talk about
4 opioid misuse or non-medical use.

5 Are you familiar with those terms?

6 A. Yes.

7 Q. How do you use "non-medical use"?
8 What does that term mean to you?

9 A. Taking an opioid in a way other than
10 prescribed. Non-medical was the terminology that
11 was more commonly used until maybe around 2014
12 when the National Survey starts using the term
13 "misuse" instead of "non-medical use."

14 Q. Either misuse or non-medical use
15 contemplates taking an opioid for a purpose other
16 than as prescribed?

17 A. It's a little -- I think it's taking
18 it in a way not prescribed. So if you have it for
19 your knee pain and you're told to take it three
20 times a day but you take it four times a day, that
21 would be considered misuse.

22 Q. It would be misuse if a teenager took
23 opioids out of a medicine cabinet without a
24 prescription and started taking them, right?

25 MS. DICKINSON: Objection to form.

1 A. Right.

2 Q. So when we talk about non-medical use
3 or misuse, we're talking about somebody who is
4 taking a prescription opioid who has not been told
5 pursuant to a prescription to take them, right?

6 A. Not exactly. It's someone who is
7 taking an opioid in a way that was not prescribed
8 to them.

9 Q. And it includes somebody who never
10 had a prescription at all, right?

11 A. Correct.

12 Q. It includes somebody who buys from a
13 street dealer?

14 A. Well, actually, I'm sorry. To just
15 go back to it includes someone who was never
16 prescribed them at all, I suppose it could, but in
17 many cases, it involves someone who had received a
18 legitimate prescription at some prior point in
19 time.

20 So we have studies that show us, for
21 example, with adolescents, that an adolescent who
22 is prescribed an opioid medically and who uses it
23 medically is much more likely to later on misuse.
24 So yeah, so misuse doesn't mean that there wasn't
25 prior legitimate medical use.

1 Q. When somebody is misusing, they are
2 not taking it pursuant to a doctor's prescription,
3 correct?

4 MS. DICKINSON: Objection to form.

5 A. An episode of misuse would mean that
6 the opioid is being taken in a way that was not
7 prescribed to them.

8 Q. Do you know of the percentage of
9 opioid use disorder that arises from misuse of
10 opioids as contrasted with iatrogenic use?

11 MS. DICKINSON: Objection to form.

12 A. I'm not aware of studies that have
13 really looked at that. What we have are specialty
14 data from the National Survey on Drug Use and
15 Health that look at the source of an opioid for
16 individuals who report non-medical use or misuse,
17 but for people who ultimately become opioid
18 addicted, I don't know that there are -- there's
19 good data -- I don't think there's good data out
20 there to tell about their first episode of use,
21 was the first time they ever used an opioid
22 medical or non-medical. I'm not aware of that
23 type of published literature.

24 Q. I wanted to not focus so much on
25 first use, I wanted to ask you about people who

1 become opioid addicted to prescription opioids.

2 Is it your understanding that most
3 people who become addicted to prescription opioids
4 have engaged in misuse? Is that your
5 understanding?

6 MS. DICKINSON: Objection to form.

7 A. It's a very difficult question to
8 answer because for some people who become
9 addicted, once their addiction develops, they
10 start to misuse opioids and take them in ways that
11 weren't prescribed, which is actually very common
12 in people who become addicted.

13 There are people who are addicted to
14 opioids who actually take them exactly as
15 prescribed by doctors. We would still consider
16 them addicted because the opioids are having a
17 harmful effect on them and they're kind of stuck
18 on them, but it's hard to tease that out
19 because -- the way you're asking the question, I
20 think you're asking me did their addiction develop
21 from misuse and that's tricky to know.

22 So, you know, was the misuse a
23 consequence of their addiction or was the misuse
24 what led to their addiction? If you'd like, I
25 could try to answer your question based on my

1 clinical experience.

2 Q. Why don't you tell me what your
3 clinical experience is?

4 A. In my clinical experience, most of my
5 older patients have given me histories that their
6 addiction developed through medical use and I've
7 treated many older adults who had never even
8 smoked a cigarette in their life, but were
9 prescribed opioids and became addicted through
10 medical use.

11 So I would say the majority of my
12 older patients, people middle-aged and up, it was
13 medical use that led to their addiction. I would
14 say in my younger patients -- my patients who are
15 mostly in their 20s, early 30s -- there, it was
16 more of a mix. I treated many patients who their
17 opioid addiction -- the history I got was really
18 opioid addiction that developed largely through
19 non-medical use, but I've also treated plenty of
20 young people who had chronic medical problems --
21 Crohn's disease, for example -- and their
22 addiction also was iatrogenic caused by medical
23 use.

24 I would say, though, for the patients
25 who gave me a very clear history of addiction that

1 began through recreational use, even for those
2 patients I don't know that I asked them
3 consistently, but I believe based on the
4 literature that many of those people where their
5 addiction developed from misuse or non-medical
6 use, I think many of them had a prior medical
7 exposure which increased the risk.

8 They basically -- many of them, I
9 believe, had their first taste of the drug from a
10 doctor or a dentist and they may have liked the
11 effect, they certainly weren't afraid of it, so
12 that made them at greater risk to misuse and
13 ultimately, they became addicted from their
14 misuse.

15 Q. So a substantial proportion of the
16 younger patients you see have addiction that in
17 your judgment has arisen out of misuse?

18 MS. DICKINSON: Objection to form.

19 A. I would say more or less yes, I think
20 yes to your -- to what you're asking. But many of
21 the individuals where that -- these young people
22 where their addiction began through really much an
23 episode of prolonged misuse and that's how they
24 got hooked, many of those individuals, I believe,
25 had some prior medical exposure that made them at

1 greater risk of misuse.

2 Q. But then your judgment is that their
3 addiction arose out of misuse, subsequent misuse?

4 MS. DICKINSON: Objection.

5 A. What I'm really saying is that that
6 initial medical exposure played a role, so it's
7 difficult to tease this out, but the period that
8 led to their really becoming severely addicted, it
9 was not from doctor -- taking doctor's
10 prescriptions repeatedly. It was through
11 diversion.

12 Q. Which is a form of misuse?

13 A. Yes.

14 Q. Your practice is an addiction
15 practice; is that right?

16 A. Yes. My specialty is treating opioid
17 addiction.

18 Q. So when you're seeing older patients
19 who are addicted to opioids and you said your
20 judgment was a number of them or many of them had
21 become addicted to opioids through iatrogenic
22 use?

23 MS. DICKINSON: Objection to form.

24 A. Yes, iatrogenic addiction.

25 Q. But from among the entirety of

1 patients treated with opioids by doctors for
2 iatrogenic use of opioids by patients, you don't
3 know the percentage that end up with an opioid
4 addiction?

5 A. As we have discussed, we don't have
6 good data to inform us on the incidence rate, to
7 tell us what percentage will become addicted when
8 they're put on opioids long term and since we
9 don't have that data, what we rely on -- all we're
10 left to rely on is prevalence data and studies
11 like the studies we have discussed -- Boscarino --
12 that have looked at the prevalence of opioid
13 addiction or Opioid Use Disorder in patients on
14 long-term opioids, you find an extremely high
15 prevalence of more than 25%.

16 MS. DICKINSON: Tim and Dr. Kolodny,
17 we've been going a little over an hour.

18 Again, Tim, when you get to a stopping point,
19 I think it's a good time for a break.

20 MR. HESTER: Okay. Let me just go a
21 little bit longer.

22 MS. DICKINSON: Sure. Of course.

23 Q. When you said -- well, actually, I
24 just got -- I lost my train of thought from that.

25 MS. DICKINSON: I'm sorry. I didn't

1 mean to interrupt you.

2 Q. Your phrase was 25%.

3 Could you explain what you just said,
4 Doctor?

5 A. Twenty-five percent or more of
6 patients on chronic opioid therapy will meet
7 criteria for opioid addiction or Opioid Use
8 Disorder and so these are studies that are looking
9 at patients already on opioids and you find that
10 Opioid Use Disorder among patients on long-term
11 opioids for pain and that condition is common.
12 And so even though we don't have good incidence
13 studies, the fact that the prevalence is so high
14 suggests that many of these patients develop their
15 addiction through -- suggests that the incidence
16 rate if we did the study would be very high.

17 Q. But when you distinguish between
18 incidence and prevalence, you're saying you don't
19 have a cause and effect relationship?

20 MS. DICKINSON: Objection to form.
21 Lacks foundation.

22 A. It's a good question. It's really
23 important here. So the incidence of a disease or
24 the incidence rate of a disease is generally
25 reported as the number of new cases of that

1 disease in a one-year period, so new development
2 of a disease is the incidence of the disease.

3 The prevalence is when you're looking
4 at how many people in a population have a disease
5 and so that's the difference.

6 Q. So when you're looking at prevalence,
7 you can observe factors in the population that has
8 a disease, but it's often difficult to separate
9 cause and effect because there may be numerous
10 factors in the population that already has the
11 disease, correct?

12 MS. DICKINSON: Objection to form.

13 A. So finding that a disease is highly
14 prevalent in a population doesn't necessarily give
15 you much information about the specific causes of
16 the disease, but when you see that this disease is
17 highly prevalent in a population that's taking
18 this particular medicine repeatedly, that's pretty
19 good evidence that that medicine may have
20 something to do with why that disease is so
21 prevalent.

22 Q. But there could be other factors as
23 well beyond taking of the medicine, correct?

24 MS. DICKINSON: Objection to form.

25 A. In terms of a prevalence study, a

1 prevalence study doesn't really get at all of the
2 factors. It's a study of a population to inform
3 us about potential causes.

4 MR. HESTER: All right. Okay.

5 I think this is an okay time for a
6 break, Erin.

7 MS. DICKINSON: Okay. Sounds good.

8 It is 11:20 your time. Do we want to
9 come back in just like five minutes and then
10 try to do a shorter segment and take a lunch
11 break?

12 Tim, I don't want to -- I don't know
13 how long you're going today and where a good
14 lunch break time is. I also don't want to
15 make Dr. Kolodny starve, so --

16 MR. HESTER: What's your typical
17 lunch break, Dr. Kolodny?

18 THE WITNESS: 12:15, 12:30 for lunch,
19 Eastern time.

20 MR. HESTER: How about if we aim
21 for -- if we come back in ten and then we aim
22 to stop for lunch around 12:30? Is that okay
23 by you?

24 THE WITNESS: That works great.

25 MR. HESTER: I hope you brought a

1 sandwich -- I hope you brought a sandwich to
2 the office.

3 THE WITNESS: I'm at my home office
4 today, so --

5 MR. HESTER: Oh, good. Okay. All
6 right. Thanks.

7 So let's come back at 11:30.

8 MS. DICKINSON: Sounds great.

9 THE VIDEOGRAPHER: The time is 11:21
10 and we are now off the record.

11 (Recess taken)

12 THE VIDEOGRAPHER: The time is now
13 11:32 and we are back on the record.

14 Q. Dr. Kolodny, let me go back on one
15 point.

16 We talked a little bit before about
17 this Volkow paper from the New England Journal of
18 Medicine, Exhibit 4.

19 Who is Nora Volkow?

20 A. The director of NIDA, National
21 Institute of Drug Abuse.

22 Q. Is she a well-regarded professional
23 in this field?

24 A. She has tremendous expertise in the
25 neurobiological basis of addiction. Particularly

1 methamphetamine addiction is her expertise.

2 Q. You know her personally?

3 A. Yes, I do.

4 Q. Have you worked with her on projects?

5 A. Not really. I don't think we've ever
6 collaborated together.

7 Q. Are her opinions -- in this area of
8 opioid addiction, is she well regarded for her
9 thinking on these issues?

10 MS. DICKINSON: Objection.

11 Form.

12 Lacks foundation.

13 A. She's well regarded in the subject of
14 the neurobiology of addiction in general and her
15 research is on methamphetamine addiction. She's
16 not known as an opioid addiction expert.

17 (Whereupon, Exhibit 13 was marked for
18 identification.)

19 Q. Let me go back to the Boscarino study
20 which you mentioned and I don't think we've marked
21 this one yet. It's Exhibit 13. Could you open
22 that, please? Do you have that one there? We
23 premarked as Exhibit 13 a paper by Joseph
24 Boscarino and others entitled "Prevalence of
25 Prescription Opioid Use Disorder Among Chronic

1 Pain Patients: Comparison of the DSM-5 versus
2 DSM-4 Diagnostic Criteria."

3 Dr. Kolodny, have you seen this
4 before?

5 A. Yes.

6 Q. This is the Boscarino report you
7 mentioned before our break?

8 A. I was discussing two reports, but by
9 Boscarino, this is -- and I think I cite both of
10 them -- but yes, this is one of the reports I was
11 referring to.

12 Q. Let me ask you to look at page 191,
13 please.

14 A. Got it.

15 Q. Maybe to set the table this is a --
16 this is a study looking at prevalence of Opioid
17 Use Disorder among chronic pain patients; is that
18 right?

19 A. I believe so, yes, in primary care
20 settings.

21 Q. And at page 191, in the left-hand
22 column, there's a statement: "The best predictors
23 of higher Opioid Use Disorder severity are age
24 younger than 65 years, history of opioid use,
25 history of high opioid withdrawal symptoms and

1 history of substance abuse treatment."

2 Do you see that?

3 A. You're reading from the bottom of the
4 page?

5 Q. Yes.

6 A. So he's referring to predictors of
7 Opioid Use Disorder severity and yeah, those
8 were -- that's what he listed there.

9 Q. To your understanding, what is this
10 meaning of predictors? What does that mean to
11 you?

12 A. Factors that could potentially
13 predict the likelihood of something happening.

14 Q. They're not necessarily cause and
15 effect factors?

16 MS. DICKINSON: Objection to form.

17 A. That's correct.

18 Q. And why are they not cause and effect
19 factors?

20 MS. DICKINSON: Objection to form.

21 A. Because what's being reported on is
22 an association, not necessarily a cause. And
23 you're looking at, you know, relative risks among
24 different factors and so -- and certainly none of
25 these factors can result in Opioid Use Disorder or

1 severe Opioid Use Disorder without an opioid. The
2 exposure that has to be there.

3 Q. When we say association and when you
4 say that phrase association means something
5 different from cause and effect, can you just
6 explain that?

7 A. Yes. You can have two variables that
8 are associated with each other, but not
9 necessarily one causing the other. In some cases,
10 the association is causal. In other cases, there
11 can just be an association.

12 Q. So an association is an observation
13 of characteristics in a population?

14 A. Yes.

15 Q. And so this population is chronic
16 pain patients with Opioid Use Disorder? That's
17 the population they're looking at?

18 A. Yes. I guess the population that
19 they're looking at would be individuals on
20 opioids, long-term opioids for chronic pain.
21 That's the population. And then they're trying to
22 compare those who did or did not develop Opioid
23 Use Disorder or even compare among the people who
24 developed Opioid Use Disorder variables that could
25 have helped predict how severe their Opioid Use

1 Disorder would become.

2 Q. If you look over at the next page,
3 please, 192, at the bottom of the right-hand
4 column, there's the last sentence on the page
5 which carries over to the next. It says "Lifetime
6 DSM-5 Opioid Use Disorder was also associated with
7 lifetime alcohol dependence, tobacco dependence,
8 major depression, Generalized Anxiety Disorder,
9 lifetime PTSD, history of childhood adversities,
10 exposure to psychological trauma, illicit drug
11 use, substance use, substance abuse treatment,
12 psychotropic medication use and a history of
13 Antisocial Personality Disorder."

14 Do you see that?

15 A. Yes.

16 Q. And again, when they're talking there
17 about associations, are they talking about factors
18 that are not necessarily causal, but are
19 associated with the population of chronic pain
20 patients who had on Opioid Use Disorder?

21 A. Yes.

22 MS. DICKINSON: Objection to form.

23 Q. Let me ask you to look at the Edlund
24 study, please, Exhibit 9. Do you have that there?
25 Exhibit 9 is in your stack we already opened.

1 A. Yes, I have it.

2 Q. Let me point you to the right hand
3 column on the first page, 557. There's a sentence
4 down at the bottom of the right-hand page --
5 right-hand column. Towards the bottom, it says
6 "Studies suggest that individuals with a past
7 history of substance abuse disorders have a higher
8 likelihood of developing OUDs."

9 Do you see that?

10 A. Yes.

11 Q. Do you agree with that?

12 MS. DICKINSON: Objection to form.

13 A. I would agree that there are studies
14 that suggest that, yes.

15 Q. Then it goes on to say "Although
16 other risk factors remain to be identified" -- do
17 you see that? It's the next clause in that same
18 sentence?

19 A. Yes.

20 Q. When they refer to risk factors
21 there, what's your understanding of that term?

22 A. A factor that could potentially
23 influence the risk of a particular outcome.

24 Q. We'll turn topics a little bit.

25 Do you agree that prescription

1 opioids do not come into a community or not out in
2 a community unless they leave pharmacies after
3 doctors have written prescriptions for them?

4 MS. DICKINSON: Objection to form.
5 Lacks foundation.

6 A. No, I wouldn't agree with that.

7 Q. Is your understanding that
8 prescription opioids cannot be sold to the public
9 and cannot be dispensed to the public without a
10 prescription?

11 MS. DICKINSON: Objection to form.

12 A. Yes. My understanding is that a
13 prescription -- that for a pharmacy to sell a
14 prescription to a patient, there needs to be a
15 prescription written.

16 Q. In particular, with respect to a
17 prescription opioid, a prescription opioid can't
18 leave a pharmacy unless a prescription has been
19 provided?

20 A. Well, unfortunately, it can --

21 MS. DICKINSON: Objection to form.
22 Go ahead, Doctor.

23 A. Unfortunately, it can, but it's not
24 supposed to.

25 Q. And when you say it can, are you

1 talking about circumstances where there's theft
2 from a pharmacy?

3 A. Theft or pharmacies selling the pills
4 out the back door.

5 Q. Okay.

6 Do you -- so let's talk about the
7 ways that prescription opioids can come into a
8 community.

9 One way is a prescription is written
10 by a doctor and the patients are given a
11 prescription for opioids, right? That's one way
12 they come into the community?

13 A. Yes.

14 Q. A second way is a pharmacy sells
15 prescription drugs out the back door without a
16 legitimate prescription?

17 A. That would be another way.

18 Q. The third way is there's theft --

19 A. I'm sorry. Or a pharmacy staff
20 person -- I mean, I wouldn't take selling out the
21 back door that literally.

22 Q. Fair enough.

23 So it would be some circumstance
24 where a pharmacy employee sells or gives
25 prescription opioids to somebody without a

1 legitimate prescription?

2 A. Yes.

3 Q. And then a third circumstance would
4 be where somebody steals prescription opioids from
5 a pharmacy?

6 MS. DICKINSON: Objection to form.

7 A. Yes, that can happen, too. I
8 wouldn't limit the universe to those three, but
9 yes.

10 Q. Well, are there other ways that
11 prescription opioids can get into a community
12 aside from the three we've just discussed?

13 A. Yes.

14 Q. What are they?

15 A. Diversion from a hospital is one way.
16 Diversion from the supply chain before the drug
17 makes it to a hospital or to a pharmacy and there
18 are probably other ways as well.

19 Q. Okay.

20 What other ways do you have in mind?

21 A. It could come into a community from
22 diversion that happens outside that community as
23 well. So if you're talking within a particular
24 community, there are lots of different ways that
25 opioids can wind up in that environment.

1 Q. Do you have any evidence with respect
2 to Cabell, Huntington, do you have any evidence of
3 prescription opioids being diverted from
4 hospitals?

5 MS. DICKINSON: Objection to form.

6 A. There's evidence of diversion from a
7 hospital pharmacy. I don't know that that --
8 there might be some other explanation for why one
9 of the hospital pharmacies had massive amounts of
10 opioids that were sold by -- there's evidence --
11 it's possible those opioids went to patients, but
12 it is also possible that there was diversion from
13 that pharmacy. What we have is a serious red
14 flag.

15 Q. Now, I wanted to ask you a very
16 specific question, though.

17 When you're using the term
18 "diversion," you're saying pills that left a
19 hospital pharmacy without a legitimate
20 prescription, right?

21 MS. DICKINSON: Objection to form.
22 Foundation.

23 A. That would be one form of diversion.

24 Q. I'm asking for that case do you have
25 any evidence of pills leaving any hospital

1 pharmacy in Huntington, Cabell without a
2 prescription?

3 A. I wasn't asked to opine on diversion
4 from hospitals in Cabell County. It's certainly
5 possible that there's good evidence out there.

6 What I am familiar with is data on
7 the opioids that the defendants sold to a variety
8 of customers, including outpatient pharmacies at a
9 hospital.

10 Q. Right.

11 Do you have -- so I take it you have
12 no evidence and you've not been asked to look at
13 the question of any pills that were diverted
14 without a prescription from hospital pharmacies?
15 You don't have evidence of that?

16 A. No, I think I have seen some
17 potential evidence of that. I've seen a red flag.
18 But I did not explore that and I was not asked to
19 opine on that.

20 Q. And do you have any evidence of
21 prescription opioids leaving pharmacies in the
22 Huntington/Cabell community without a legitimate
23 prescription? In other words, some mechanism by
24 which they left the pharmacy without a legitimate
25 prescription?

1 MS. DICKINSON: Objection to form.

2 A. I've seen evidence in the form of
3 data on sales to pharmacies that suggest
4 diversion. From the data that I've reviewed, I'm
5 not really able to opine on the type of diversion,
6 whether it was a pharmacy employee selling the
7 drug or pharmacy employee filling a prescription
8 from a pill mill. From the data that I looked at,
9 I can't really answer your question.

10 Q. You've not been asked to provide an
11 opinion on the amount of such diversion?

12 MS. DICKINSON: Objection to form.

13 Lacks foundation.

14 A. I was not asked to investigate or
15 opine on the specific forms of diversion that
16 occurred.

17 Q. Do you have any evidence of
18 prescription opioids being diverted from the
19 supply chain before the opioids reached a
20 pharmacy?

21 MS. DICKINSON: Objection to form.

22 A. I'm not sure. I can't recall whether
23 or not I've come across documents. I know I have
24 certainly seen evidence that the defendants in
25 this case were cited and had their DEA

1 registrations suspended for activities that
2 occurred at distribution centers and so, you
3 know -- but exactly what happened at those
4 distribution centers, was it simply a failure to
5 report suspicious orders at these distribution
6 centers or was there also diversion directly from
7 the distribution centers, I can't recall.

8 Q. And you've not been asked to opine on
9 the question of whether there was diversion from
10 distribution centers before prescription opioids
11 reached the pharmacies?

12 A. That's correct. I wasn't asked to
13 opine on that.

14 Q. So you're not aware yourself of any
15 prescription opioids that were in the
16 Huntington/Cabell community that were in that
17 community other than because of a legitimate
18 prescription?

19 MS. DICKINSON: Objection to form.

20 Lacks foundation.

21 Q. It's a convoluted question. If you
22 want me to ask again, I can try a little better.

23 A. Okay.

24 Q. I wanted to ask you about the supply
25 of prescription opioids in Huntington/Cabell.

1 Are you aware yourself of any
2 evidence that the supply in Huntington/Cabell was
3 in that community for any reason other than
4 because of prescriptions written by doctors?

5 MS. DICKINSON: Objection to form.

6 A. Your previous question you asked --
7 you used the term "legitimate" and I am aware that
8 there were pill mill doctors in Cabell County and
9 so I wouldn't consider their
10 prescriptions legitimate. If you are asking about
11 supply that came through routes other than a
12 prescription filled at a pharmacy, off the top of
13 my head, I wasn't asked to opine on that, so I'd
14 really have to go back and look more closely at
15 some of the data that I did have access to, but --
16 so it's very hard for me to answer that question.

17 Q. It's not something you're being asked
18 to opine on, what percentage of pills in the
19 community were there because of prescriptions that
20 were legitimate versus illegitimate versus
21 diversion? That's not something you're opining
22 on?

23 A. I think I can opine on that. I can
24 certainly opine on the fact that there were
25 literally millions of pills sold by the

1 defendants, billions of MMEs sold by the
2 defendants in the county and so that's clear
3 evidence of prescriptions that were written or
4 pills that left pharmacies for illegitimate
5 reasons.

6 There's no way that Cabell County
7 could have had a legitimate need for billions of
8 MMEs, so that is evidence of a serious problem.

9 Q. Now, but I wanted to ask a slightly
10 more specific question, which is have you been
11 asked to opine -- I'm asking what you were asked
12 to opine on.

13 Have you been asked to opine on the
14 mix of pills -- prescription opioids -- that were
15 in Cabell/Huntington because of legitimate
16 prescriptions written by doctors as compared to
17 diversion from various sources? Have you been
18 asked to opine on that?

19 MS. DICKINSON: Objection to form.

20 Lacks foundation.

21 A. I was asked to -- I think that the
22 subjects that I was asked to opine on would
23 broadly include that. I was not asked to try and
24 estimate what percentage of the prescriptions
25 could be legitimate versus illegitimate or

1 specific -- what percentage of diversion might
2 have been from a specific route.

3 Q. And again, just to make it clear, you
4 understand that there's a closed system of
5 distribution when a distributor distributes
6 prescription opioids to a pharmacy? That's a
7 closed system. You understand that?

8 A. Yes, I understand that there is
9 supposed to be a closed system and that the
10 defendants in this case were responsible for
11 ensuring where they could that that system would
12 remain closed, but that there was not a closed
13 system.

14 Q. Are you aware of any instance where a
15 distributor -- where pills were diverted between a
16 distributor and the time they reached a pharmacy?
17 Do you have any evidence of that?

18 MS. DICKINSON: Objection to form.

19 A. I have clear evidence that there was
20 not a closed system. Where the exact leaks
21 occurred in the system, I was not asked to opine
22 on.

23 Q. Okay.

24 Again, you don't have any evidence of
25 distributors failing to deliver prescription

1 opioids to a pharmacy that was entitled to receive
2 them?

3 MS. DICKINSON: Objection to form.

4 A. I'm sorry. Could you ask that
5 question again?

6 Q. Yes. It's backwards.

7 Do you have any evidence of instances
8 where there was a diversion of pills from a
9 distributor before they reached a pharmacy that
10 was entitled to receive them?

11 MS. DICKINSON: Objection to form.

12 A. I might have evidence. Off the top
13 of my head, I don't recall seeing specific
14 examples of diversion between the distribution
15 center and the pharmacy.

16 Q. Let me ask you to look at page 86 of
17 your report, please. At the very bottom of the
18 page, you refer to prescription opioids flowing
19 into West Virginia communities at levels that
20 could never be considered clinically warranted.

21 Do you see that?

22 A. I do.

23 Q. And when you say clinically
24 warranted, how do you make that judgment?

25 A. So as we talked about previously,

1 many of the pills that flowed into Cabell and
2 Huntington were written for 30-milligram immediate
3 release oxycodone tablets. There were other
4 high-strength opioids that the defendants sold,
5 but there were massive amounts of 30-milligram
6 immediate release oxycodone.

7 As I mentioned previously, that's --
8 one 30-milligram immediate release oxycodone is
9 equal to nine Vicodin in a single pill. We've
10 talked about the appropriate uses of opioids where
11 for someone maybe near the end of life with
12 metastatic cancer who's been on opioids for maybe
13 several months or for a year as their cancer
14 progressed, there could be cases where they might
15 be on very high doses of opioids because of the
16 tolerance and you had to keep going up on the
17 dose.

18 It makes no sense that in Cabell
19 County you would have so many individuals with
20 metastatic cancer requiring 30-milligram
21 oxycodone. The amount of those pills is clear
22 evidence that either inappropriate prescriptions
23 were written or there was diversion. It could not
24 have been clinically needed, that amount of
25 oxycodone.

1 You know, maybe I'd give one caveat:
2 If the world's largest hospice center moved into
3 the county, treating patients from around the
4 planet, you know, maybe you could justify it based
5 on those numbers.

6 Q. Are you focusing particularly on the
7 30 mg Oxycontin? Is that the particular point
8 you're making?

9 A. Thirty and 50-milligram oxycodone are
10 extremely high dosage products and it's not really
11 just that. It's also the quantity of the lower
12 dosage pills, like Hydrocodone. How much acute
13 pain could there really have been? If you look at
14 the appropriate use of opioids even for acute pain
15 in other countries, opioids are really not given
16 to patients when they go home from the hospital.
17 They're not using even the low dose in those
18 quantities.

19 So again, even the massive amount of
20 Hydrocodone in lower dosage pills suggests that
21 the pills flooding into the county could not have
22 been clinically warranted.

23 Q. You refer to the lower doses being in
24 excess of what would be seen in other countries.

25 Were the lower dose pills going into

1 the community comparable to levels that you'd see
2 in other communities in the United States?

3 A. No. Higher. So we know that West
4 Virginia is not just an outlier for opioid-related
5 morbidity and mortality. We know that West
6 Virginia is also a state where there's been much
7 greater amounts of opioids that have flooded into
8 the state and a pretty consistent finding when you
9 compare geographic areas where the opioid crisis
10 may be more severe than -- it's just exactly what
11 I've said: Where there are more opioids, you see
12 more opioid-related morbidity and mortality.

13 Q. Have you done a study of how many
14 pills would be clinically warranted?

15 A. I haven't performed a study, but I
16 have studied that subject and I've published on
17 appropriate use of opioids and if you're asking
18 me, I would say that the level of consumption in
19 the United States in the 1980s was appropriate and
20 by the early 90s, we start -- it starts to go up
21 and it really takes off in the mid 90s.

22 So if I had to really draw a line
23 somewhere, I would -- the most conservative place
24 to draw that line would be levels of consumption
25 after 1996 when it starts soaring up. What you're

1 adding on to what we were consuming before 1996
2 was clinically unwarranted.

3 Q. And so your judgment is any levels
4 higher than 1996 are clinically unwarranted?

5 A. That's a conservative estimate
6 because even in 1996, we had already had some
7 significant growth in opioid consumption and in
8 the early 90s, international comparisons would
9 suggest we were overconsuming opioids in the
10 United States, but 1996 is really an inflection
11 point where the consumption takes off dramatically
12 and so I think it's a conservative place to draw
13 the line.

14 Q. So you would agree that the levels in
15 1996 would be a clinically warranted basis,
16 clinically warranted levels?

17 A. I would say that if I'm going to be
18 really conservative and try and define where the
19 consumption is likely to be clinically
20 unwarranted, I would draw that line in 1996 and
21 say what came into the county after 1996 -- if you
22 use 1996 as a benchmark -- would be inappropriate,
23 but that would be a very conservative estimate
24 because consumption was already pretty high in
25 1996.

1 Q. Were there -- in your view -- any
2 subsequent evolution in the -- was there a
3 subsequent evolution in thinking about the need
4 for better treatment of pain in the United States
5 since 1996?

6 THE COURT REPORTER: Erin, you're
7 muted. Are you objecting?

8 MS. DICKINSON: I was. That's okay.
9 Objection to form.

10 Thank you, Sara.

11 MR. HESTER: Nice catch.

12 THE COURT REPORTER: I saw your lips
13 moving. I just wasn't sure.

14 Q. My question is was there a change in
15 thinking about the need for better treatment of
16 pain in the United States in 1996.

17 MS. DICKINSON: Objection to form.

18 A. I would say there was a change in the
19 thinking about opioid use for pain that was --
20 resulted from a deceptive industry campaign to
21 change the way the medical community thought about
22 opioids for pain and that campaign was very
23 effective and is why we started to see -- one of
24 the main reasons we started to see this dramatic
25 shift in opioid prescribing that starts to happen

1 in 1996.

2 Q. I understand your opinion about the
3 engagement of manufacturers in the industry in
4 relation to thinking on pain.

5 I want to separate that out and I
6 want to ask you a separate question, which is put
7 aside the influences of Purdue, other opioid
8 manufacturers or what have you.

9 I want to ask is it your view that
10 there was an appropriate enhanced focus on pain
11 treatment after the mid 90s?

12 MS. DICKINSON: Objection to form.

13 A. No, I don't think so. I think in the
14 80s there was evidence that we needed to do a
15 better job with palliative care and not even
16 necessarily prescribing more opioids to people who
17 were near the end of life from cancer, but just
18 that there were ways to help people die with more
19 dignity and be more comfortable.

20 But I don't believe that from 1996
21 onward that all this -- the messaging that we had
22 an epidemic of chronic pain in America or that
23 millions of Americans were suffering needlessly
24 because doctors don't adequately address pain, I
25 believe that was part of this manufactured

1 campaign by the opioid industry. And not just
2 opioid manufacturers. When I say opioid industry,
3 I'm really talking about all of the players.

4 Q. Do you also agree there was an
5 evolution in thinking among the medical community
6 separate and apart from the influence of the
7 industry of opioid manufacturers? Was there an
8 evolution in thinking separate and apart about the
9 importance of pain treatment?

10 MS. DICKINSON: Objection to form.

11 A. It's not really possible because when
12 the medical community is hearing from professional
13 societies that are promoting opioids and key
14 opinion leaders that are promoting opioids and
15 accreditation agencies, when all of these messages
16 are coming to the medical community about opioids
17 and behind all of these messages are organizations
18 with financial ties to the opioid industry,
19 organizations that are sitting at the table with
20 opioid manufacturers and distributors, I don't
21 know how you can really tease that out.

22 I will say that there are many
23 individuals out there and possibly organizations
24 promoting these messages because they believed it
25 was the right thing to do and --

1 Q. I'm sorry.

2 A. -- I think they were being
3 influenced.

4 Q. But you agree there were doctors who
5 are making their own judgment that pain treatment
6 was something that needed to be improved?

7 MS. DICKINSON: Objection to form.

8 A. There were doctors who were making
9 that judgment based on information that's coming
10 to them from every direction. From every
11 direction we're hearing that patients are
12 suffering needlessly because of an irrational fear
13 of opioids and that the risk of addiction is
14 extremely low and that it's normal and appropriate
15 to put people with backaches on long-term opioids.

16 Q. I'm not asking about -- I'm not
17 asking about the appropriate treatment. I'm
18 asking about the importance of treating pain and
19 was there an increased recognition that it was
20 important to treat pain.

21 MS. DICKINSON: Objection to form.

22 A. But not really separate from this
23 whole campaign. Part of this push to increase
24 prescribing involved creating a perception that
25 we're not doing a good job of treating pain and

1 millions of patients are suffering.

2 I don't believe that that perception
3 was based on evidence. I believe that you had a
4 manufactured need and that's what doctors are
5 hearing, that if you're a compassionate doctor in
6 the know, you're going to recognize that people
7 with pain haven't been getting their pain treated
8 adequately and you can do a better job. I don't
9 believe that the medical community was failing to
10 treat pain appropriately, though, before 1996.

11 Q. The prevailing view in the medical
12 community after 1996 was that there was a need to
13 put more emphasis on pain treatment, right?

14 A. And it's happening a little bit
15 before 1996, but it really takes off after 1996.
16 The medical community is hearing from every
17 direction that we need to do this and many
18 well-meaning clinicians are buying into this and
19 teaching it to younger doctors and there are a lot
20 of people who are genuinely falling for these
21 messages, but I don't believe that there was a
22 real need.

23 Q. Let me ask you to look at the
24 Sullivan paper, Exhibit 2. That's not a new one.
25 It's one we've opened before.

1 A. I got it.

2 Q. So let me -- at the very bottom of
3 the first page, he says "The ethical mandate for
4 pain relief as basic care has been extended from
5 end of life to all cancer pain."

6 Do you see that?

7 MS. DICKINSON: I'm sorry.

8 Tim, what page?

9 MR. HESTER: Page one. I'm sorry.

10 MS. DICKINSON: Okay.

11 MR. HESTER: Bottom of that first
12 page.

13 Q. Do you see that statement?

14 A. I'm on the first page of the paper,
15 the cover --

16 Q. It's under the heading of
17 "Introduction."

18 A. Yes, okay.

19 Q. It's the last sentence on the page:
20 "In subsequent years, the ethical mandate for pain
21 relief is basic care has been extended from end of
22 life to all cancer pain."

23 A. Yes.

24 Q. Is that a reflection of what you
25 called the well-meaning or well-intentioned view

1 that there needed to be increased emphasis on pain
2 treatment?

3 MS. DICKINSON: Objection to form.

4 A. I'd kind of have to read through the
5 whole paragraph. Let me get a better sense of
6 what he's trying to communicate in that sentence.

7 Is that okay?

8 Q. Sure.

9 A. Yes.

10 Q. Then, if you look over on page two,
11 the second full paragraph begins "The above
12 arguments for pain management as a fundamental
13 human right have addressed pain treatment
14 broadly."

15 Do you see that?

16 A. Where on page two are you?

17 Q. It's the start of the second full
18 paragraph. They refer to pain management as a
19 fundamental human right.

20 A. Okay.

21 Q. Do you see that?

22 A. Yes, I see that sentence.

23 Q. So again, does this reflect what you
24 were referring to as the evolution of well-meaning
25 doctors in thinking more about pain as something

1 that needed to be managed?

2 MS. DICKINSON: Objection to form.

3 A. I'm sorry. I'm not following your
4 question.

5 Q. So you had referred to the fact that
6 doctors were hearing from every corner about the
7 need to increase pain treatment and that this was
8 something that many well-meaning doctors
9 assimilated into their thinking and into the
10 medical school courses they were teaching, etc.

11 A. Yes.

12 Q. And so my question is is this a
13 reflection of the point that there was an
14 evolution -- a well-meaning evolution -- in
15 thinking about the fundamental right of pain
16 treatment?

17 MS. DICKINSON: Objection to form.

18 A. I'm not really sure if this is a good
19 example of that.

20 Q. Would you put Sullivan in this
21 category of people you were talking about,
22 well-meaning doctors who thought it was important
23 to focus more on pain treatment?

24 A. I might put him in a little bit of a
25 different category. He's -- so many doctors who

1 work in a particular specialty generally see
2 themselves as advocates for people with that
3 condition and so if you ask a psychiatrist, you
4 know, what are the most urgent public health
5 problems in America, they'll tell you untreated
6 depression and so part of that is just a bias we
7 all have of seeing our own clinical field as being
8 something that's exceptionally important and
9 doesn't get enough attention and we have to do
10 better in it. We advocate for it for the
11 conditions that we treat.

12 Dr. Sullivan is a psychiatrist whose
13 focus has been on improving care for people with
14 chronic pain, which is why he's also done work to
15 highlight how much -- the extent to which patients
16 with chronic pain are harmed by aggressive opioid
17 prescribing, but a lot of his career has focused
18 on improving treatment of pain, especially
19 reducing opioid use.

20 Q. But he's focusing here on this
21 growing importance of putting more emphasis on
22 treating pain?

23 A. I think a lot of -- you know,
24 certainly if you -- my comments earlier were
25 really referring to what the medical community was

1 hearing, the primary care community.

2 If you were someone working in the
3 field of pain, your research grants are for pain
4 research, this is what you've dedicated your
5 career to, you're going to view this all probably
6 in a more positive light.

7 Yes, what we're working on is getting
8 more attention, but objectively, were people with
9 chronic pain better off in the early 90s? I think
10 if you asked Dr. Sullivan, he'd say yes, that we
11 have harmed many people by promoting this concept
12 that we were under treating pain, particularly
13 opioids.

14 Q. But there was a change in the medical
15 community in thinking about the need to be more
16 effective in treating pain? There was that change
17 in thinking?

18 A. The thinking about pain and treatment
19 of pain and opioids in particular did change
20 dramatically.

21 Q. After 1996?

22 A. Yes.

23 Q. And you had mentioned before that
24 your judgment about how many prescription opioids
25 are clinically warranted could be affected by

1 clinics and so forth that were in a particular
2 community, right?

3 MS. DICKINSON: Objection to form.
4 Lacks foundation.

5 MR. HESTER: I'll ask it a slightly
6 different way if it's cleaner.

7 Q. Do you agree with me that the
8 judgment about how many prescriptions could be
9 medically warranted in a community could be
10 influenced by the nature of the hospitals and
11 clinics operating in that community?

12 MS. DICKINSON: Objection to form.

13 A. I'm still struggling with your
14 question.

15 Q. Well, if you had -- I believe you had
16 said before that if there were an extremely large
17 facility dealing with end-of-life care in
18 Huntington/Cabell, that could affect the level of
19 pills that would be clinically warranted in that
20 community, correct?

21 MS. DICKINSON: Objection to form.
22 Lacks foundation.

23 A. Yeah, but I did give an example of if
24 the world's largest hospice moved into the
25 community and patients from around the planet were

1 traveling into the community to have their
2 end-of-life cancer pain treated, it could
3 potentially be clinically warranted. But I was
4 really -- the point I was trying to communicate is
5 that it's not feasible that the amount of -- that
6 the billions of MME flowing into the county, the
7 millions of pills could have been clinically
8 warranted.

9 Q. Have you done the study of what the
10 facilities were in the community? What kind of
11 pain clinics, hospices and other facilities there
12 are in the Huntington/Cabell community? Have you
13 looked at that?

14 A. Again, it's not -- it wouldn't make a
15 difference. It's not feasible that there are
16 types of treatment, hospitals or settings where
17 this -- that could explain all of those
18 30-milligram immediate release oxycodone tablets
19 or the vast quantity, the dosage of those
20 Hydrocodone pills.

21 It's just not feasible, so it
22 wouldn't require study. The --

23 Q. I asked you a simple question.
24 Have you done that study?

25 A. I wouldn't study something that

1 doesn't really make sense to study. It's on
2 the -- it's just -- it's not feasible.

3 Q. Yeah, but you haven't done the study
4 of what the facilities are in that community?

5 A. I wouldn't do a study on whether or
6 not parachutes are effective.

7 Q. Well, it's a little bit different,
8 right?

9 If there are five large hospice
10 facilities in a community, you might think there
11 would be more clinically warranted pills than if
12 there were none, correct?

13 A. It's possible that the type of
14 treatment symptoms in a particular community could
15 influence consumption in that community. That's
16 possible. But the amount that flowed into the
17 county could not be explained by having more
18 hospices. The numbers are astronomical.

19 Q. Do you know the share of
20 prescriptions that were for the 30 mg oxycodone
21 and the 50 mg oxycodone?

22 MS. DICKINSON: Objection to form.

23 A. I have data in my report on the
24 amount of -- on the different dosage units that
25 were prescribed that I could -- I'd be happy to

1 consult that.

2 Q. Okay.

3 And that includes the share, the
4 share of those -- a share of the dosages at that
5 level versus others?

6 MS. DICKINSON: Objection to form.

7 A. The data on consumption or on dosage
8 units on MMEs sold by the distributors in the
9 county came in different formats and so I would
10 just want to -- it's a pretty long report. I'd
11 want to consult that before answering your
12 question.

13 Q. Well, I may look for it over lunch
14 and see if I could find it.

15 Individual judgments are made by
16 individual doctors about the prescriptions they
17 believe are clinically warranted for their
18 patients, correct?

19 A. Yes.

20 Q. And the total number of prescriptions
21 that are written in a particular community reflect
22 the amalgamation of the judgments of those
23 individual doctors about the prescriptions that
24 they believe are clinically warranted for their
25 patients, correct?

1 MS. DICKINSON: Objection to form.

2 A. Not necessarily.

3 Q. Well, if for one doctor -- when one
4 doctor writes prescriptions for the patients he or
5 she is serving, those prescriptions reflect that
6 judgment -- that doctor's judgment about what's
7 clinically warranted, right?

8 MS. DICKINSON: Objection to form.

9 A. Not necessarily.

10 Q. The doctors are not making the
11 judgments about what's clinically warranted?

12 MS. DICKINSON: Objection to form.

13 A. Not necessarily.

14 Q. You think doctors don't make -- when
15 a doctor writes a prescription, you think the
16 doctor is not making a personal judgment about
17 what is clinically warranted?

18 A. I would hope that all doctors would,
19 but that's not always the case.

20 Q. Well, but that's what doctors are
21 charged with doing, correct? They're charged with
22 writing prescriptions that are clinically
23 warranted?

24 A. Correct. That's what we're all
25 supposed to do, but unfortunately, there are

1 doctors who become drug dealers and they're not
2 necessarily prescribing what they believe is in a
3 patient's best interest.

4 Q. So I want to put aside -- I want to
5 put aside a doctor who is a drug dealer or a
6 doctor who would be a pill mill. I want to ask
7 about doctors who are running legitimate practices
8 and making legitimate prescription decisions.

9 For those doctors, you agree they're
10 making their own judgments about what's clinically
11 warranted?

12 MS. DICKINSON: Objection to form.

13 A. Not necessarily.

14 Q. The doctors are not making their own
15 judgments about what's clinically warranted?

16 MS. DICKINSON: Objection to form.

17 A. Not necessarily. Would you like me
18 to give you an example?

19 Q. Yes.

20 A. So a doctor may be unclear about
21 what's in a patient's best interest, so that
22 doctor may contact a pharmacist or may consult
23 colleagues and unfortunately, if that doctor is
24 consulting someone with bad judgment or someone
25 with a financial incentive to give that advice, it

1 could influence what's done for that patient.

2 Q. Are you aware of any circumstances
3 where doctors call pharmacists to get advice on
4 what to prescribe?

5 A. Yes. Extremely common. I've done it
6 in my clinical practice. If there's a medication
7 I need to prescribe -- I generally treat
8 addiction. If I have a patient with a rash and
9 I'm -- they need a steroid cream and I want to
10 help the patient, I may contact the pharmacist and
11 say "Hey, what's a high potency topical steroid
12 for my patient with poison ivy?"

13 So it's extremely common for doctors
14 and hospitals to work with the hospital pharmacist
15 and doctors who work in the community to
16 communicate and take advice from the pharmacist in
17 that community.

18 Q. But the doctor isn't calling to ask
19 whether the highest steroidal cream should be
20 prescribed, but is asking what cream would be the
21 right one, correct?

22 MS. DICKINSON: Objection to form.

23 A. In the example I gave you for myself,
24 I might have an idea that the patient with poison
25 ivy needs a topical steroid and I might ask what's

1 a good high potency topical steroid, but a doctor
2 could easily call a pharmacist and say "I have a
3 patient with a rash, a patient with bad poison ivy
4 and the over-the-counter stuff is not working.
5 What would you suggest I prescribe?"

6 That, I believe, is probably a very
7 common conversation and it could also similarly be
8 "I have a patient with terrible back pain who
9 tried the over-the-counter stuff. What would you
10 recommend?"

11 Q. You think doctors are making
12 judgments about controlled -- prescription of
13 controlled substances by calling pharmacies?

14 A. I know that doctors consult
15 pharmacists frequently and if you -- and I believe
16 if you were to ask your own pharmacist experts
17 whether or not that happens routinely, I think
18 your experts will tell you it does.

19 Q. You think that a doctor would call a
20 pharmacy to get a recommendation on prescribing --
21 on whether to prescribe a controlled substance?

22 That's your testimony?

23 A. I believe that doctors frequently
24 talk with pharmacists about what to prescribe,
25 that pharmacists can influence physician

1 prescribing practices, including controlled
2 substances.

3 You can send a patient to the
4 pharmacy and they don't have what you prescribed
5 because it wasn't stocked. You could send your
6 patient to the pharmacy, you wrote a prescription
7 for Oxycontin, the pharmacy doesn't have Oxycontin
8 and they tell the doctor "Look, we've got Vicodin,
9 but we don't have Oxycontin."

10 That happens all of the time and I
11 believe your own experts will acknowledge that.

12 Q. But the doctor makes the initial
13 judgment about whether or not the patient should
14 be prescribed a controlled substance, right?

15 A. Not necessarily.

16 Q. You think doctors are not making
17 those judgments?

18 A. I think that doctors consult
19 pharmacists about -- frequently -- about what to
20 prescribe, including controlled substances. Even
21 the dose. A doctor may not know what doses a
22 particular medication comes in. They call the
23 pharmacy and they say "Hey, what's the starting
24 dose for XYZ drug?" and the pharmacist will tell
25 them or they'll say "What's the frequency for this

1 drug? Is it every 12 hours?"

2 When a doctor has to write a
3 prescription for a drug that they're not familiar
4 with that they don't write frequently, they very
5 often will talk to a pharmacist.

6 Q. But the doctor is ultimately charged
7 with deciding whether the prescription is
8 clinically warranted, right?

9 A. The doctor and the pharmacist. The
10 pharmacist is not supposed to dispense a drug that
11 is not clinically warranted.

12 Q. But the prescription is supposed to
13 be written by the doctor who makes the judgment
14 that is clinically warranted, right?

15 A. That's correct.

16 Q. So when the doctor makes the judgment
17 that it's clinically warranted for the patient,
18 that's when the prescription can be written,
19 correct?

20 A. The prescription should reflect what
21 a doctor believes is clinically warranted.

22 Q. Then you have a collection of doctors
23 who write prescriptions. The total volume of
24 prescriptions across that collection of doctors
25 reflects the combination of judgments by all those

1 doctors about the prescriptions that are
2 clinically warranted, right?

3 A. Not necessarily.

4 Q. Because you think they're not
5 adhering to what they are obliged to do?

6 MS. DICKINSON: Objection to form.

7 A. In some cases, you've got a very
8 large percentage of prescriptions being written by
9 doctors who aren't doing what's in the best
10 interest of their patient.

11 Particularly with opioids, we've got
12 good evidence that something like 20% of
13 prescribers in a given area are prescribing 80% of
14 the opioids and so the way that you're asking the
15 question, it's as if the total amount of opioids
16 reflects the view of all of the doctors in a given
17 community.

18 When it comes to opioids, just a
19 handful of doctors that are operating pill mills
20 or a pain management practice that's in a gray
21 area -- is it really a pill mill or not -- can it
22 have a tremendous impact on consumption in a given
23 community.

24 Q. Yes, but if a doctor is running a
25 legitimate pain clinic, the doctor is going to be

1 more likely to write more treatments -- more
2 prescriptions for pain treatment, correct?

3 MS. DICKINSON: Objection to form.

4 A. No, not really. I think a doctor who
5 is running a legitimate pain clinic is doing
6 everything they can to try and help get patients
7 off of opioids and address their pain with other
8 modalities.

9 Q. But you would agree with me that a
10 doctor who runs a pain clinic -- a legitimate pain
11 clinic -- is more likely than a doctor who is in a
12 different kind of practice to be writing more pain
13 prescriptions?

14 MS. DICKINSON: Objection to form.

15 A. That's hard to say. I do think that
16 there are doctors with legitimate pain clinics who
17 are writing prescriptions for opioids because the
18 patients come to them hooked on the opioids and
19 they can't just stop them. So yeah, maybe you
20 would see a fair amount of opioid prescribing in a
21 legitimate pain clinic.

22 But if it's really a legitimate pain
23 clinic, you're seeing a reduction in opioid use in
24 a given patient.

25 Q. But you agree with me over time that

1 what you are seeing is doctors are prescribing
2 fewer opioids, right?

3 MS. DICKINSON: Objection to form.

4 A. Yes. So fortunately, the -- we're
5 trending in the right direction. Doctors are
6 beginning to get the message and we're still
7 unfortunately massively overprescribing, but the
8 trend is in the right direction, which is
9 positive.

10 Q. And that trend reflects judgments
11 being made by doctors about when opioids are
12 clinical warranted, correct?

13 MS. DICKINSON: Objection to form.

14 A. That would be a part of it, maybe
15 even a small part of it. Taking a license away
16 from a doctor like Anita Dawson, who was
17 prescribing massive amounts, also changes.

18 So when I talk about the prescribing
19 trending in the right direction, I'm really basing
20 that on consumption trends in the United States
21 and where we first saw the biggest dip in
22 consumption trends is when there was a crackdown
23 on pill mills in Florida. Oxycodone for the
24 United States dropped when we started closing down
25 pill mills.

1 So a lot of that change is not
2 necessarily a change due to doctors making better
3 judgments. Some of it is to putting doctors who
4 were drug dealers out of business. So it's a
5 variety of factors, but there is --

6 Q. But one factor is doctors making
7 clinical judgments about when opioids are
8 warranted, right? That's a factor in the decline
9 of prescription opioid use?

10 A. Doctors being better able to weigh
11 risks versus benefits is one of the factors, yes.

12 Q. Let me ask you --

13 MS. DICKINSON: We're a little over
14 where we were going to stop. I don't want to
15 exhaust Dr. Kolodny and/or starve him, but,
16 again, if you have a few questions that you
17 want to finish up, certainly go ahead and
18 then we'll break.

19 MR. HESTER: No, I think this is
20 probably a good time to take a break.

21 MS. DICKINSON: Okay. Sounds good.

22 When do you all want to come back?
23 Dr. Kolodny is in his home, so I think we
24 could be back relatively quickly, but Tim,
25 what do you need?

1 MR. HESTER: Same for me. I'm in my
2 house, too. Life in the pandemic. I could
3 come back in half an hour, but if you want
4 more time, we could do that too.

5 It's a little bit your schedule, Dr.
6 Kolodny, what you want to do.

7 THE WITNESS: I'm good with whatever
8 works best for everybody.

9 MR. HESTER: Erin, what do you want
10 to do?

11 MS. DICKINSON: Why don't we try to
12 come back in a half an hour, give or take.
13 You know, if Dr. Kolodny is not in the chair,
14 we will wait five minutes, but let's give it
15 a shot.

16 It's 12:35 Eastern, so let's try for
17 1:05 and if we get back a few minutes later
18 than that, we're all fine.

19 THE VIDEOGRAPHER: The time is 12:35
20 and we're now off the record.

21 (Recess taken)

22 THE VIDEOGRAPHER: The time is 1:06
23 p.m.

24 We are now back on the record.

25 Q. Dr. Kolodny, let me ask you to look

1 at page 53 in your report, please.

2 A. Got it.

3 Q. So this is data on pharmacies in
4 Cabell and Huntington, right?

5 MS. DICKINSON: Objection to form.

6 A. Yes.

7 Q. I'm sorry.

8 Shipments to pharmacies in Cabell and
9 Huntington, right?

10 A. Yes.

11 Q. It's based on ARCOS data?

12 A. I believe so, yes.

13 Q. You know that the three distributor
14 defendants in this case didn't have access to the
15 ARCOS data? Do you know that?

16 MS. DICKINSON: Objection to form.

17 Lacks foundation.

18 A. I know that the DEA wasn't routinely
19 sharing ARCOS data, but ARCOS data was available
20 to researchers and could be FOIA'd.

21 The type of the data that was
22 available through ARCOS -- actually, even better
23 data than ARCOS -- was certainly available to the
24 defendants through IMS, which is now IQVIA, so --
25 I don't know that it's totally accurate to say

1 they didn't have access to ARCOS data.

2 Q. Do you know whether distributors were
3 permitted to have access to ARCOS data?

4 A. There's ARCOS data that could be
5 FOIA'd and there have been research publications
6 using ARCOS data. So I don't know that -- so some
7 ARCOS data may have been available to
8 distributors. I'm not certain.

9 I am aware, though, that the
10 distributors have argued that they didn't have
11 access to ARCOS data and therefore they
12 couldn't -- they didn't have a complete picture of
13 what was happening. I'm aware of that argument
14 that they made, which I don't give much credence
15 to.

16 Q. Do you know whether there were any
17 other distributors aside from McKesson, Cardinal
18 and ABDC operating in Cabell and Huntington?

19 A. Yes, I believe there were other
20 distributors.

21 Q. And do you know whether the three
22 defendants in this case -- Cardinal, ABDC and
23 McKesson -- supplied all of these pharmacies you
24 listed?

25 A. I don't know that they supplied all

1 these pharmacies. I believe that the big three
2 were responsible for the bulk of what was -- what
3 came into the State of West Virginia and into
4 Cabell County.

5 Q. But you don't know about these
6 pharmacies in particular?

7 A. I don't know the breakdown for each
8 of these pharmacies for their suppliers and I
9 would imagine some might have changed over time
10 where one distributor would stop supplying them
11 and they'd get filled through another distributor.

12 Q. Do you know anything about these
13 pharmacies other than what you read in the
14 Rafowski report?

15 A. You know, I read about this from the
16 McCann report and also the Rafowski report. I
17 don't know if I'm aware of information about these
18 specific pharmacies from sources other than those
19 reports. I don't think I am.

20 Q. Do you know whether any of the
21 pharmacies on this list served hospice patients?

22 A. I don't know if any of the pharmacies
23 on this list had as a -- had a hospice or hospice
24 patients as customers. No, I don't know. But it
25 wouldn't -- certainly wouldn't change my opinion

1 unless, of course, they were serving the enormous
2 hospice or an enormous number of hospices.

3 Q. Do you know whether any of these
4 pharmacies served long-term care facilities like
5 nursing homes?

6 A. I don't know, but I don't think it
7 would have changed my opinion because I'm looking
8 at the dosage unit, the MME and so -- but I
9 haven't really looked at lists of clients.
10 Certainly if that information was available, I'd
11 be happy to look at it and opine on it. I don't
12 think it would change my opinion.

13 Q. But you haven't looked?

14 MS. DICKINSON: Objection to form.

15 A. I have not opined on or looked at the
16 breakdown or the customers, but I don't -- I don't
17 believe it would affect my opinion because, as we
18 discussed previously, the number of pills --
19 hundreds of millions of opioids that came into the
20 county, billions of MMEs that came into the
21 county -- I can't see how that -- how you could
22 have had long-term care facilities or hospices
23 that could account for this.

24 And even in a long-term care
25 facility, those are generally nursing homes.

1 Nursing homes would not -- should not require lots
2 of opioids. You don't want to give patients with
3 dementia or patients who are frail lots of
4 opioids. That's generally a very bad idea.

5 So the only potential explanation
6 would be the world's largest hospice has just
7 moved to Cabell County.

8 Q. I was asking a narrow question,
9 whether you looked at it. I wasn't asking whether
10 it changed your opinion, just to be clear on that.
11 Because it will take us too long to get through it
12 if we don't focus on the questions I'm asking.

13 Let me ask you to look at 57 to 58 of
14 your report. This is where you are discussing two
15 doctors who issued lots of opioid prescriptions,
16 right?

17 A. Yes.

18 Q. I take it you don't know where these
19 doctors' patients filled their prescriptions? You
20 don't know where or which pharmacy they went to?

21 A. I'm not -- I don't know with
22 certainty and don't have that data in front of me,
23 but I could -- pill mill doctors, their patients
24 went to -- a legitimate pharmacy wouldn't have
25 been filling their prescriptions, so in all

1 likelihood, the pill mill doctors prescriptions
2 were filled at some of the pharmacies that
3 accounted for the highest amount of opioids
4 dispensed.

5 Q. But you don't know that? You're just
6 assuming that?

7 MS. DICKINSON: Objection to form.

8 A. I don't have a list of these doctors'
9 patients and where they're -- I should say
10 customers, rather than patients.

11 I don't have a list of where they
12 filled their prescriptions.

13 Q. Do you know if Cardinal, ABDC or
14 McKesson supplied any of the pharmacies where
15 those prescriptions were filled?

16 A. I do know --

17 MS. DICKINSON: Objection to form.

18 A. I do know that the big three sold
19 Hydrocodone and oxycodone to some -- to outlier
20 pharmacies in the county and pill mill doctors,
21 their patients or customers have prescriptions
22 that are filled at outlier pharmacies because
23 legitimate pharmacies won't fill prescriptions of
24 pill mill doctors.

25 So although I don't have the direct

1 evidence in front of me, I believe it's very
2 likely that the big three sold pills to pharmacies
3 that filled these prescriptions.

4 Q. But you already said you don't know
5 which pharmacies these patients filled their
6 prescriptions at, right?

7 A. I do not have a list of all of the
8 pharmacies that the customers of these pill mills
9 went to to have their prescriptions filled.

10 Q. So you also can't know whether
11 Cardinal or ABDC or McKesson supplied any of those
12 pharmacies because you don't know which ones they
13 were?

14 MS. DICKINSON: Objection to form.

15 Asked and answered.

16 A. I have a report here and I have seen
17 data showing that the big three supplied outlier
18 pharmacies in the county and it was outlier
19 pharmacies where customers of pill mills went to
20 have their prescriptions filled, so I believe it
21 is very likely that the big three sold pills to
22 outlier pharmacies that filled prescriptions for
23 these doctors and I believe --

24 Q. Sorry. Go ahead.

25 A. Go ahead. I'm sorry.

1 Q. Well, you're just reasoning that
2 through. You don't -- I'm just trying to nail
3 down a specific question.

4 You don't know whether the doctors --
5 these two doctors were writing prescriptions that
6 were being filled at pharmacies that were supplied
7 by Cardinal, ABDC or McKesson. You don't know
8 that.

9 MS. DICKINSON: Objection to form.
10 Asked and answered now several times.

11 MR. HESTER: No, I don't think he's
12 answered it, so --

13 MS. DICKINSON: You're not liking his
14 answer, but he is answering it.

15 Dr. Kolodny, you could try again.

16 Q. I mean, you don't know. You're
17 drawing a logical assumption, but you don't know.

18 MS. DICKINSON: Objection to form.
19 Argumentative.

20 A. So I do know that legitimate
21 pharmacies were not filling prescriptions written
22 by pill mill doctors and so patients or customers
23 of pill mills, they received -- they got their
24 pills from outlier pharmacies and I do know that
25 the defendants in this case supplied outlier

1 pharmacies in the county. So that's the
2 information I have available.

3 And it is possible that there's more
4 data available that I don't recall seeing, but
5 basically that's my best answer at this time.

6 Q. What's your basis for your statement
7 that pill mill doctors would not have the
8 prescriptions they wrote filled at legitimate
9 pharmacies?

10 A. So I've been treating opioid
11 addiction for many years and some of my patients,
12 before they were in treatment or when they were in
13 treatment and remained in touch with friends who
14 were not in treatment, were getting opioids from
15 pill mills and I learned from my patients, even
16 before there was data available to support this,
17 that when you had a prescription written by a pill
18 mill doctor, it was hard to get that prescription
19 filled at a legitimate pharmacy.

20 When a healthy looking 25-year-old
21 walked into a pharmacy with cash and a
22 prescription for 240 tablets of 30-milligram
23 immediate release oxycodone, most pharmacists
24 would say "Get the hell out of here." So these
25 individual patients or even sometimes professional

1 rings would have to find the pharmacies that were
2 willing to fill these prescriptions.

3 I've learned from my patients that
4 often the pill mill would say "Hey, go to this
5 particular pharmacy. That's where you won't have
6 trouble."

7 And so the pharmacies that were
8 willing to fill these outrageous prescriptions
9 would very quickly start to become outlier
10 pharmacies and so that's part of the basis for my
11 opinion.

12 Q. Any other basis?

13 MS. DICKINSON: Objection to form.

14 Q. Do you have other information aside
15 from what you've learned from your patient base --

16 MS. DICKINSON: Objection to form.

17 Q. -- to support the proposition that
18 pill mill doctors would have prescriptions filled
19 only at rogue pharmacies?

20 MS. DICKINSON: Objection to form.

21 Foundation.

22 A. Just to be clear, that wasn't my
23 position, that they would only have them filled.
24 It was that they would generally only be able to
25 get these prescriptions filled out outlier

1 pharmacies.

2 In the example that I gave you of a
3 healthy looking young person with a wad of cash,
4 those patients generally had a hard time getting
5 prescriptions filled at legitimate pharmacies.

6 I can't say always or never, but I'm
7 telling you what I believe happened routinely and
8 there's evidence that came out I believe in the
9 trial against -- was it SafeScript? -- where the
10 owner of pharmacy was convicted in part for
11 filling prescriptions for pill mill doctors.

12 There have been reports in the media,
13 law enforcement investigations. So it's not just
14 based on my clinical experience. It's based on
15 other available evidence.

16 Q. And the available evidence is things
17 you've read in the media or the testimony from
18 SafeScript?

19 A. I would say work by investigative
20 journalists, I believe part of this was covered in
21 an investigation by the House Energy and Commerce
22 Committee and from my knowledge from working on
23 the opioid crisis for many years as an expert.

24 So from a variety of sources, my
25 opinion that outlier pharmacies were filling

1 prescriptions from pill mill doctors, I think it
2 is based on lots of information.

3 Q. The patient base that you serve in
4 your practice is based around New York City; is
5 that right?

6 A. That's correct.

7 Q. So you haven't worked with patients
8 in the -- in West Virginia who may have been
9 receiving prescriptions from pill mill doctors,
10 right?

11 A. I haven't treated patients in West
12 Virginia, but I've talked with patients in West
13 Virginia, I've talked with doctors in West
14 Virginia, I've been to West Virginia on multiple
15 occasions and a part of West Virginia adjacent, I
16 believe, to Cabell County and so no, I didn't
17 treat patients in West Virginia, but I have had
18 firsthand experience learning about the opioid
19 crisis in West Virginia.

20 Q. Are you aware of the fact that
21 patients who get prescriptions from pill mill
22 doctors often went to different pharmacies to
23 disguise the volumes they were getting? Are you
24 aware of that?

25 A. I'm aware of the fact that a patient

1 or an individual who has opioid addiction and is
2 receiving prescriptions for multiple prescribers
3 will often visit multiple legitimate pharmacies,
4 so -- and pay cash usually for the second or third
5 prescription, use their insurance for the first
6 prescription -- that is common.

7 But if a patient is visiting a pill
8 mill, there may not be a need for what's often
9 termed doctor shopping. If you're visiting one
10 doctor and you're paying that doctor for an
11 extremely large and inappropriate prescription,
12 you don't have to shop around.

13 Q. Let me turn you to page 25 of your
14 report.

15 Do you have that?

16 A. It's in front of me.

17 Q. The chart at the bottom of the page
18 shows a line for West Virginia oxycodone sales and
19 US oxycodone sales per hundred thousand people,
20 right?

21 A. That's correct.

22 Q. It reflects that there's been a drop
23 of more than 50% -- I'm sorry -- roughly a drop of
24 50% in oxycodone sales in West Virginia?

25 MS. DICKINSON: Objection to form.

1 Lacks foundation.

2 A. It looks like -- what you're saying
3 looks about right from the graph, but I haven't
4 done the math.

5 Q. I was doing the math by seeing that
6 it was more than -- it was above 30 in 2014 and
7 2013 and 2012 and then it's below 15 by 2019.
8 That's how I was getting the math of a 50% drop.

9 Is that right? Is that your
10 understanding?

11 A. It looks about right.

12 Q. And now, your chart is showing that
13 the sales for oxycodone in West Virginia are about
14 the same level as they are nationally in the
15 United States, right?

16 A. That's correct.

17 Q. Let me ask you the same question on
18 26 of your report, page 26.

19 It shows more than a 50% drop in
20 Hydrocodone sales in West Virginia; is that right?

21 A. Yes, from the peak.

22 (Whereupon, Exhibit 7 was marked for
23 identification.)

24 Q. Right.

25 Let me ask you to look please at

1 Exhibit 7, which is a new one for you.

2 A. Got it.

3 Q. Have you seen this letter from the
4 AMA before?

5 I should maybe just set the
6 foundation. This is a document we premarked as
7 Exhibit 7, a letter from the American Medical
8 Association to Deborah Dowell of the National
9 Center for Injury Prevention and Control dated
10 June 2020.

11 Have you seen this document before?

12 A. I may have.

13 Q. Let me ask you to look at page two of
14 the document, please.

15 Do you see the first bullet on the
16 page? It says "Opioid prescriptions decreased 33%
17 between 2013 and 2018, including more than 12%
18 between 2017 and 2018 alone."

19 Do you see that?

20 A. Yes, I do.

21 Q. Is that consistent with your
22 understanding of the decline in opioid
23 prescriptions across the country?

24 MS. DICKINSON: Objection to form.

25 A. I think so, yes.

1 Q. Are you aware of any more recent
2 trends -- here we are in 2020. Are you aware of
3 any more recent trends in declines in opioid
4 prescriptions in the US since 2018, 2019? Are you
5 aware of anything more recent?

6 MS. DICKINSON: Objection to form.

7 A. I'm not sure if I've seen anything
8 published with more current data on prescribing.
9 I'm not certain. Off the top of my head, I can't
10 think of any more current data.

11 The opioid prescribing trends -- I'm
12 just trying to think on the slides that I show --
13 I think generally ends around 2018.

14 Q. Is it your understanding that the
15 trend is continuing to go down?

16 A. I don't know. I'm concerned that
17 it's not. It's hard to say. There's been an
18 effort to preserve the status quo of aggressive
19 prescribing and how successful that effort has
20 been recently, I'm not sure.

21 It's also hard to say what is
22 happening in the context of COVID. Is that
23 causing an increase in opioid prescribing, a
24 decrease. There's been some deregulation of
25 opioid prescribing in the context of COVID, so I

1 wouldn't want to speculate on what's happening
2 currently with opioid prescribing trends.

3 Q. Have you looked at any more recent
4 trends in opioid prescribing in West Virginia in
5 particular?

6 A. I don't think I've seen any very
7 current data on opioid prescribing trends in West
8 Virginia. I certainly hope that it's continuing
9 to trend in the right direction.

10 Q. This trend that we've been discussing
11 that's reflected in your charts, in your report
12 and in this data out of the AMA letter, that trend
13 reflects a greater focus on judgments being made
14 by doctors about risks and benefits of opioids.

15 Is that your understanding of it?

16 MS. DICKINSON: Objection to form.

17 A. I think that the trend is related to
18 better clinical decision making and possibly law
19 enforcement efforts and medical board efforts that
20 have put criminals -- it's probably both factors.

21 Q. You would attribute at least some of
22 this decline to decision making by individual
23 doctors that lead to this decline?

24 A. I think increasingly the medical
25 community is better weighing risks versus benefits

1 when it comes to opioid prescribing.

2 Q. But the medical community, at the
3 same time, is continuing to engage in a
4 substantial level of opioid prescribing, right?

5 MS. DICKINSON: Objection to form.

6 A. Yes. There continues to be massive
7 overprescribing in the United States. We continue
8 to prescribe far more than any other country on
9 earth and there are current papers published with
10 data, I think, from maybe even as recent as 2019.
11 International comparisons -- I wouldn't call it a
12 trend because it's more of a snapshot or a
13 six-month period and it's not trying to trend it,
14 but it's trying to do an international comparison
15 and there still are no other countries that come
16 even close.

17 Q. Would you also agree with me that
18 there's quite meaningful differences between US
19 medical care and other countries in relation to
20 prescription medicines generally?

21 MS. DICKINSON: Objection to form.

22 A. Opioids are not the only medicines
23 that are overprescribed in the United States. So
24 there are definitely differences. I'm talking
25 about countries that are doing -- where evidence

1 would suggest that they may be doing a better job
2 of treating pain and these are countries that
3 prescribe much less opioids.

4 Q. Let me ask you to look at the first
5 page of the AMA letter, please.

6 So the third paragraph, the statement
7 by the AMA is "The nation no longer had a
8 prescription opioid-driven epidemic."

9 Do you see that?

10 A. I do.

11 Q. Do you understand the basis for the
12 AMA's conclusion on that point?

13 A. I think if you think about the opioid
14 crisis as being all about the deaths involving
15 opioids and if you sum up the national data on
16 deaths in the past few years involving
17 prescription opioids have come down a little bit.
18 It's hard to, again, know what's happening right
19 now, but what's really caused a surge in
20 opioid-related overdose deaths has been illicitly
21 synthesized fentanyl. Prescription opioids are
22 heroin are about neck and neck.

23 So if you think the opioid crisis is
24 really all about people dying from opioids, you
25 might say well illicit opioids are now worse than

1 prescription opioids. But if you understand that
2 the opioid crisis is really an epidemic of opioid
3 addiction fueled by overexposing the population to
4 prescription opioids, if you understand that the
5 reason we have record high levels of
6 opioid-related overdose deaths is because of the
7 prevalence of opioid addiction increased and that
8 many of the people now with opioid addiction have
9 transitioned to illicit use, then you really
10 wouldn't use this kind of terminology.

11 Q. Have you taken issue with the
12 statement by the AMA that the nation no longer has
13 a prescription-driven opioid epidemic?

14 MS. DICKINSON: Objection to form.

15 A. I think it's sloppy language.

16 Q. So you wouldn't agree with it?

17 A. The United States -- the United
18 States is in the midst of a severe epidemic of
19 opioid addiction caused by overexposing the
20 population to prescription opioids. If you were
21 to ask me whether or not nationally illicit opioid
22 deaths outnumber prescription opioid deaths, I
23 would agree with you.

24 But if you look at people who have
25 become opioid addicted post 1996, the vast

1 majority of them developed their addiction taking
2 prescription opioids, so if you frame the problem
3 as all about the deaths, then that language can
4 maybe make some sense.

5 But if you understand that the opioid
6 crisis is an epidemic of opioid addiction, you
7 recognize that the epidemic of opioid addiction
8 was fueled and continues to be fueled by
9 prescription opioids.

10 Q. So this statement, though, the nation
11 no longer has a prescription opioid-driven
12 epidemic, this statement by the AMA, you don't
13 agree?

14 A. I don't like that language. I think
15 that's -- and it suggests -- whoever is using that
16 language, it suggests that they don't have a good
17 understanding of the opioid crisis. I don't
18 believe experts who study the opioid crisis would
19 use that type of language.

20 Q. So this is written by the CEO of the
21 AMA on behalf -- on behalf of AMA, right?

22 A. Yes. And Dr. Madara has written
23 other letters on opioids which similarly reflect a
24 misunderstanding of the opioid crisis and that
25 don't necessarily jive with what many of AMA

1 members believe or doesn't necessarily jive with
2 some of the work that AMA has done on this issue.
3 Dr. Madara's positions on opioids in the past have
4 been more in line with the opioid industry.

5 And I would also point out that the
6 AMA opioid task force, which I think has had some
7 influence here, includes the American Academy of
8 Pain Medicine, which I think is fairly
9 characterized as an opioid industry front group
10 which even your experts have pointed to that
11 organization's consensus statement as one of the
12 reasons that opioid prescribing improperly took
13 off and that group has some real influence on
14 letters like this that the AMA will contribute.

15 Q. Yeah. I was just asking a narrow
16 question, though.

17 You disagree with this statement?

18 A. I think it -- I don't believe that
19 that statement would be supported by experts who
20 study the opioid crisis. It reflects a
21 misunderstanding of the problem.

22 Q. Okay.

23 Let me ask you to look at your
24 report, page 20, please.

25 Do you have that?

1 A. It's in front of me, yes.

2 Q. This chart -- this is kind of a
3 simple question, I hope.

4 This chart, on the middle of the page
5 that shows drug overdose deaths, that's not
6 limited to prescription opioid deaths, right? It
7 includes all drug overdose deaths?

8 A. I believe that's all drugs, not just
9 prescription opioids and not just opioids. I
10 believe that's just drug overdose deaths. I think
11 it would include methamphetamine.

12 Q. Then look over at page 21, please.

13 Again, similar question: The chart
14 you show here, opioid drug overdose, that includes
15 illicit opioids such as heroin and fentanyl,
16 right?

17 A. I believe it does. I have to go back
18 to the source that I was citing, but I believe
19 this -- I believe this is all opioids, not just
20 prescription opioids. I was citing a report
21 focused on prescription opioids. I'm not really
22 certain.

23 Q. Okay.

24 But you also understand a little more
25 broadly that, as we just discussed, the rate of

1 deaths from prescription opioid overdoses has been
2 declining somewhat and the increase has been
3 fueled by overdose deaths from heroin and illicit
4 fentanyl, right?

5 MS. DICKINSON: Objection to form.

6 Lacks foundation.

7 A. I think that I may have the data. I
8 can't say with certainty the extent to which
9 prescription opioid deaths are declining or where
10 prescription opioid heroin and illicit fentanyl --
11 off the top of my head, I can't really say how
12 they compare to each other, but I would agree with
13 you that in the past few years, the soaring
14 increase in opioid-related overdose deaths in the
15 State of West Virginia have largely been driven by
16 illicitly synthesized fentanyl.

17 Q. Right. Okay.

18 Then over on page two, I think,
19 again, it's a similar clean up question.

20 At the end of the top paragraph, it
21 says in 2018, Cabell County had the highest opiate
22 overdose death rate of any county in the nation.

23 That, again, is including all opiate
24 overdose deaths, including illicit fentanyl and
25 heroin, right?

1 A. I believe so, because I think if I
2 meant prescription opioids, I would have written
3 prescription opioids. If I write opioid, I'm
4 referring to all three.

5 (Whereupon, Exhibit 14 was marked for
6 identification.)

7 Q. Right. That was my assumption, too.
8 I just wanted to confirm that.

9 Could you look at Exhibit 14? This
10 is another one we need to open. Let me -- maybe
11 let me pause, just to set the table. This is a
12 document we premarked. It's Exhibit 14.

13 It's a document written by Amy
14 Bohnert and others, "Association Between Opioid
15 Prescribing Patterns and Opioid Overdose-Related
16 Deaths."

17 Is this a document you've seen
18 before?

19 A. I have to open it up. The one in
20 this envelope?

21 Q. Yes. Sorry. I didn't know you
22 hasn't opened it yet. Sorry.

23 A. I thought you were referring me to
24 page 14 before, not exhibit --

25 Q. I'm with you.

1 So is this Exhibit 14 something
2 you've seen before, Dr. Kolodny? I can say that
3 it's cited in your report.

4 A. Yes, I'm familiar with this paper.

5 Q. Who is Amy Bohnert?

6 A. Amy Bohnert is a researcher. She's
7 done some good work on the opioid crisis
8 prescribing.

9 Q. Let me ask you to look at page 1317,
10 please.

11 A. Yes.

12 Q. At the very bottom, she writes "We
13 therefore approximated the rate of overdose among
14 individuals treated with opioids to be 0.04%."

15 Do you see that?

16 A. No. So I'm on page 1317 --

17 Q. The bottom of the right column.

18 A. Okay. We therefore approximated the
19 rate of overdose among individuals treated with
20 opioids to be 0.04%. Yes.

21 Q. She's reporting here on a study of
22 individuals who died of a prescription opioid
23 overdose during the years 2004 to 2008, correct?

24 A. I know this paper, I've cited this
25 paper, not just in support, but in other papers

1 that I've written, but it's been a little while
2 since I've read it, so I would -- I really would
3 need just maybe a moment to skim through this.

4 Q. Yeah. The place where I could point
5 you probably -- I mean, look at whatever you need,
6 but the top of the results is what I was
7 paraphrasing.

8 A. Okay. Let me just -- let me just
9 have a few minutes to refresh my memory on this
10 paper.

11 Okay.

12 Q. So this is a study of opioid overdose
13 deaths among patients who were treated with
14 opioids?

15 A. Yes.

16 Q. And she concluded that the rate of
17 overdose deaths among patients treated with
18 opioids was 0.04%; is that right?

19 A. Yes.

20 MS. DICKINSON: Objection to form.

21 Q. And is that consistent with your
22 understanding of what the rates are of overdose
23 deaths among patients treated with opioids?

24 MS. DICKINSON: Objection to form.

25 A. No, not really. I think there are --

1 this study wasn't really designed to answer that
2 question. The objective of this question was
3 really to examine the risk of high doses of
4 opioids on an ultimate death and they found in
5 this study -- they found that of the 752 deaths,
6 11 -- of the 1,136 individuals who died, 752 of
7 them received prescription opioids during this
8 period of time.

9 So I don't think they report on that
10 incidence rate, but that's not -- that wasn't the
11 objective of this paper and there are other
12 studies that give -- I think that were designed to
13 answer the question.

14 In general, though, if you look at
15 the percentage of people exposed to opioids that
16 ultimately died of an opioid overdose, it tends to
17 be a very low number because most -- we're
18 exposing millions of Americans on an annual basis
19 to opioids. The percentages that wind up dying
20 ultimately of an opioid-related overdose at some
21 point compared to the number that got prescribed
22 an opioid does tend to be very low.

23 But when you have studies that have
24 compared a population exposed to opioids versus
25 the patients that never got an opioid, to look at

1 what was the risk of ultimately dying of an opioid
2 overdose if you had been prescribed opioids, you
3 see a dramatic increase in someone who received a
4 legitimate opioid prescription compared to someone
5 who never did and ultimately died of an opioid
6 overdose.

7 So I think they're reporting on the
8 finding, I think this is good research, but you're
9 picking out a percent here that has nothing to do
10 really with the objective of this study, which was
11 to look at the impact of high doses ultimately on
12 opioid-related deaths.

13 Q. They did report this particular
14 finding about this percentage, correct?

15 A. They did, but that doesn't really
16 inform us on the percent of people that ultimately
17 die of an opioid overdose after having been
18 exposed to an opioid.

19 Q. Well, she was looking at that
20 population, right? She was looking at a
21 population that was exposed to opioids and
22 measuring the percent of those people that ended
23 up dying of an opioid overdose, right?

24 A. She looked at people who were treated
25 during a particular period of time and looked at

1 another point of time when deaths might have
2 occurred. That really, though, doesn't answer a
3 question about how many people that got a
4 legitimate prescription wound up losing their life
5 from an overdose.

6 Q. Okay. Let me switch topics a bit.

7 I wanted to ask you about suspicious
8 order monitoring programs, which is something you
9 discuss in your report.

10 I take it you're not an expert in
11 suspicious order monitoring programs, are you?

12 MS. DICKINSON: Objection to form.

13 A. So I have expertise in the opioid
14 crisis and some expertise in diversion of opioids,
15 both from my research and from my clinical
16 experience, as we talked about, so I do believe I
17 have expertise in this area and can comment on
18 suspicious ordering.

19 Q. Do you have any expertise in the
20 federal rules and regulations that govern the
21 distribution of controlled substances?

22 A. Yes, I do have some expertise in the
23 requirements for distributors to have systems in
24 place that would allow them to identify an outlier
25 pharmacy, to immediately flag that pharmacy, to

1 report that pharmacy and not fill the order.

2 So I do have an understanding of the
3 law and the impact that the failure of opioid
4 distributors to follow the law, what has happened
5 from that.

6 Q. Sorry.

7 You are not a lawyer?

8 A. I am not a lawyer.

9 Q. And when did you first look at the
10 rules and regulations that govern the distribution
11 of controlled substances?

12 A. I -- probably going back to 2003 from
13 the first work I was doing on the opioid crisis,
14 on expanding access to opioid addiction treatment
15 with buprenorphine and advocacy work on up
16 scheduling of Hydrocodone combination products, so
17 I've had familiarity with the Controlled
18 Substances Act for the past years.

19 Q. Have you ever done any work on
20 compliance issues for the distribution of
21 controlled substances?

22 A. I've never worked for an opioid
23 distributor in their compliance division.

24 Q. And you've never worked in developing
25 a suspicious order monitoring system, have you?

1 A. I have worked on the development of
2 red flags for opioid -- risky opioid prescribing
3 and the development of monitoring systems on
4 prescribing based on PDMP data, which is related,
5 but I have not ever worked for a distributor or
6 been consulted by a distributor on how they should
7 go about complying with the requirement by law
8 that they have a system in place to identify
9 inappropriate orders.

10 Q. And I take it for the same reason
11 you've never audited a suspicious order monitoring
12 program to evaluate whether it complies with
13 federal laws and regulations?

14 A. I've never audited the systems that
15 distributors are required to have by law that
16 those systems that clearly failed.

17 Q. Have you ever been consulted about a
18 distributor's suspicious order monitoring program
19 outside the context of being an expert in this
20 litigation?

21 A. No.

22 Q. I take it you've never worked for a
23 manufacturer of controlled substances, right?

24 A. No.

25 Q. You said you never worked for a

1 distributor of controlled substances?

2 A. Correct.

3 Q. Have you worked for any company that
4 was in the distribution chain for controlled
5 substance?

6 A. I mean, I've been a -- I've worked in
7 hospitals and hospitals are DEA registrants,
8 hospitals that have pharmacies, work closely with
9 hospital pharmacists, even the hospital
10 pharmacists involved in ordering the drugs.

11 So I think that's a yes.

12 Q. Have you ever worked for a pharmacy?

13 A. I've never been an employee of a
14 pharmacy.

15 Q. When did you first learn about the
16 suspicious order monitoring programs of Cardinal,
17 ABDC and McKesson? When did you first learn about
18 them?

19 MS. DICKINSON: Objection to form.

20 A. I think I first learned about them in
21 2011 maybe. I think it was when action was taken
22 by the DEA against Cardinal Health and CVS for two
23 Florida pharmacies where literally millions of
24 pills were flowing out of those pharmacies and I
25 think that was maybe the first time I started to

1 learn about the requirements for distributors to
2 have a system in place that would detect a
3 suspicious order instead of fill it and DEA took
4 action against Cardinal Health.

5 Q. Have you ever read a specific
6 suspicious order monitoring program of Cardinal,
7 ABDC or McKesson? Have you ever read any of their
8 program documents?

9 A. I've seen in discovery a
10 communication about these systems.

11 Q. Have you read any of them?

12 A. I've read internal communications
13 about these systems. For example, your client had
14 an internal communication about the monitoring
15 system where the communication was basically we're
16 in the business to sell -- to sell products and so
17 let's come up with a way that we don't have to
18 report a suspicious order. Let's increase the
19 thresholds --

20 Q. I think that wasn't my question.

21 My question was have you read their
22 specific program documents?

23 MS. DICKINSON: Objection.

24 Form.

25 A. I believe that I have. I've

1 certainly read public communications about these
2 systems which were deceptive communications about
3 these systems that would suggest they were
4 effective when the distributors knew very
5 well that they were ineffective, so --

6 Q. I think you know you're not answering
7 my question.

8 My question is have you read their
9 specific programs?

10 MS. DICKINSON: Objection to form.

11 Q. It's a yes or no.

12 MS. DICKINSON: Objection to form.

13 You asked if he read the specific
14 program documents and he is mentioning --

15 MR. HESTER: Then he's answering --
16 Erin, he's answering about public
17 communications about the documents. That's
18 not my question.

19 Q. My question, Doctor, is have you read
20 the documents -- the program documents --
21 themselves?

22 MS. DICKINSON: Objection to form.

23 A. So I have reviewed probably thousands
24 of pages of documents in the course of offering
25 opinions on this case and I believe that those

1 pages included descriptions of these systems.
2 What comes more readily to my mind is -- are the
3 internal communications about these systems and
4 the public communications about these systems, but
5 I do believe I've seen the descriptions of these
6 systems themselves.

7 Q. Are you aware that the suspicious
8 order monitoring programs changed over time?

9 MS. DICKINSON: Objection to form.

10 A. Yes, I'm aware that over time --
11 well, I don't know how much they really changed,
12 but I'm aware that the defendants in this case
13 claim that they were changing.

14 Q. Do you know what the changes were?

15 MS. DICKINSON: Objection to form.

16 A. Well, I know what's been claimed
17 about the changes. What was claimed is that they
18 had previously been in some cases relying on
19 subjective judgment of staff who had probably a
20 financial incentive to fill orders and that they
21 had moved to more objective mechanisms for
22 detecting suspicious orders.

23 Q. Do you know what any of those
24 objective mechanisms are?

25 A. I know by law that there are some

1 requirements that -- for coming up with those
2 mechanisms based on thresholds, based on changes
3 in threshold, based on what's happening in a given
4 community, so I have some knowledge about what
5 they are required to be based on.

6 But from the internal communications
7 that I've read, I'm suspicious that these
8 mechanisms were really put in place effectively
9 when staff were saying we're in the business to
10 sell, let's find ways of changing the threshold so
11 we could continue to sell.

12 Q. I understand you want to add that
13 point. I want to ask you something very specific,
14 though, about what you looked, which is do you
15 know what the changes were that were made in the
16 programs?

17 MS. DICKINSON: Objection to form.

18 A. So I am aware that the defendants in
19 this case have claimed that their systems were
20 previously too subjective and have become
21 objective. I am not sure if -- I don't really
22 think one can trust what they're saying about
23 these systems, considering their track record.

24 Q. Do you know whether there were
25 changes to make the standards more objective?

1 MS. DICKINSON: Objection to form.

2 A. I believe that changes were made.
3 Certainly your client has claimed it made changes,
4 but your client hasn't really been honest to the
5 public or even to Congress about its role, so I
6 don't know what they've actually done. I know
7 only what they're really saying that they've done.

8 Q. Okay.

9 So you've not reviewed the different
10 program documents to figure out whether objective
11 measures were put in place over time in the
12 programs?

13 MS. DICKINSON: Objection to form.

14 A. I understand what the defendants in
15 this case are communicating. The defendants in
16 this case are saying that they now have better
17 systems in place, they have acknowledged
18 publically and even apologized to the people of
19 West Virginia for the failure of their systems in
20 the past. They say they've fixed them. I hope
21 that they're not lying.

22 Q. And you don't know one way or the
23 other?

24 A. I don't know if anyone would really
25 know for certain what's happening, particularly

1 when we're talking about companies that have been
2 dishonest in their public communications on this
3 topic.

4 Q. And how do you decide that a company
5 has been dishonest? What have you looked at to
6 decide that the companies were dishonest about
7 their suspicious order monitoring programs? What
8 are you looking at to make that judgment?

9 A. Testimony before Congress. Your
10 client, the CEO of McKesson, testified before
11 Congress that we drive the truck, we do nothing to
12 influence prescribing or demand or we don't market
13 or promote.

14 That's a blatant lie and we -- we
15 know that for years the defendants in this case
16 and their trade association were communicating to
17 the public that they have effective systems in
18 place and yet we're getting cited and paying
19 million dollar fines after making those
20 communications because they didn't have systems in
21 place.

22 Q. So your conclusion about
23 misrepresentations is based on reading statements
24 that were made and concluding that they can't have
25 been right?

1 MS. DICKINSON: Objection to form.
2 Lacks foundation.

3 A. So the CEO of McKesson testifies
4 before Congress that McKesson doesn't promote or
5 market drugs --

6 Q. I'm asking about suspicious order
7 monitoring programs.

8 A. I'm talking about why I can't
9 necessarily trust what the defendants in this case
10 are saying about their systems.

11 When the CEO of McKesson is lying
12 before Congress about what its company does and
13 the role that it played, it's very difficult to
14 trust their communication.

15 So I do know, to answer your
16 question, that the defendants in this case claim
17 that they have fixed their broken systems. I
18 don't know if that can be trusted or not.

19 Q. And you don't know if it's true or
20 not?

21 A. I don't know how we can tell whether
22 or not they're telling the truth this time.

23 Q. And what do you say was false in the
24 statement by the McKesson CEO?

25 A. The McKesson CEO lied to Congress,

1 told Congress that McKesson does logistics.
2 Basically communicated we drive the truck, we do
3 nothing to influence demand, we do not promote or
4 market. More or less, those were his words and
5 that is an absolutely false statement.

6 We know that McKesson and the other
7 defendants in this case marketed and promoted
8 opioids. They all had an array of services that
9 they sold to manufacturers to help them market and
10 promote, so that is just one example of a false
11 statement and I think it's an especially important
12 example because if a CEO of one of these companies
13 is going to perjure himself before Congress, how
14 can we really trust what's being communicated
15 today about the effectiveness of these systems.

16 Q. Well, Dr. Kolodny, you're making a
17 serious charge and you're basing that on
18 reading -- reading testimony and making a judgment
19 that it's not correct.

20 Is that true? That's the way you're
21 making that judgment?

22 MS. DICKINSON: Objection to form.

23 A. I'm making a judgment that a false
24 statement was made before Congress, that McKesson
25 doesn't market or promote and that's a false

1 statement. That's not true. McKesson has
2 marketed and promoted opioids.

3 Q. And your assertion is that the CEO --
4 you've read the CEO's testimony and your
5 conclusion is it's incorrect?

6 A. Incorrect is a bit of an
7 understatement.

8 Q. So let me go back to asking you about
9 suspicious order monitoring.

10 You're saying you don't know whether
11 or not the companies have put in place more
12 objective standards for their suspicious order
13 monitoring programs?

14 MS. DICKINSON: Objection to form.

15 A. What I know is that the defendants in
16 this case are communicating publically that they
17 have fixed their broken systems. I hope that
18 that's true. I would like to think that in the
19 context of certainly the litigation against them
20 and the hundreds of millions of dollars in fines
21 that they've paid in the past for failing to have
22 systems in place that maybe right now they really
23 have fixed these systems, but I don't think we
24 could necessarily take them at their word.

25 Q. So -- and you haven't looked for the

1 underlying facts to evaluate whether it's correct
2 or not, what they said about the suspicious order
3 monitoring programs?

4 MS. DICKINSON: Objection to form.

5 A. I think -- I have not reviewed an
6 independent evaluation by a regulator of the
7 current systems that are in place. Maybe such
8 a -- maybe there is a recent evaluation by the DEA
9 of the systems that are currently in place. I
10 haven't seen that. That would help me, you know,
11 if -- that would help me make a decision about the
12 effectiveness today of these systems.

13 Q. Let me ask you to look at page 78 of
14 your report. At page 78, in the middle, you cite
15 the CSA and you say each distributor owes a duty
16 to protect the public health and safety by
17 maintaining effective goals against diversion.

18 Do you see that?

19 A. I do.

20 Q. The diversion you're talking about
21 there is diversion between the distributor and the
22 delivery to a pharmacy that's authorized to
23 receive the drugs; is that right?

24 MS. DICKINSON: Objection to form.

25 A. Just give me a moment. Okay. Yes.

1 Can you ask the question again?

2 Q. Is the diversion that you're talking
3 about in that sentence diversion of prescription
4 opioids between the time that the distributor has
5 them in its possession and delivers them to a
6 pharmacy that's entitled to receive them? Is that
7 the diversion you're talking about?

8 MS. DICKINSON: Objection to form.

9 A. No. I think that it's broader. So
10 the requirement of the law is that there's a
11 closed system and that DEA registrants all have
12 their part to play in ensuring that there's a
13 closed system and so I don't believe that the
14 distributor's responsibilities end at where they
15 drop off the pills at the pharmacy and that
16 they're only required to ensure that the system is
17 closed from point A to point B. I think their
18 responsibility is broader than that.

19 Q. And it includes what kind of
20 diversion?

21 MS. DICKINSON: Objection to form.

22 A. Dirty pharmacies -- that once they
23 get that shipment diverting from pharmacies that
24 are filling pill mill prescriptions, I believe
25 that the distributors are required by law not to

1 supply narcotics to DEA registrants who on their
2 end are not helping to keep the system closed.

3 Q. That's your understanding of what
4 their obligation is? That they cannot deliver to
5 a DEA registrant?

6 A. My understanding --

7 MS. DICKINSON: Objection to form.

8 A. My understanding is that there's a
9 requirement for there to be a closed system and
10 that DEA registrants across that closed system are
11 all responsible for ensuring that that system
12 stays closed and it's my understanding that the
13 responsibility of the distributors to help ensure
14 that that system remains closed doesn't end at
15 dropping off the narcotics at the pharmacy, that
16 their responsibilities are broader than that.

17 Q. Are you aware of another use of the
18 term "diversion" which includes, for instance,
19 circumstances where a family member or a friend
20 gives prescription opioids to somebody else who
21 doesn't have a prescription? You're aware of that
22 use of the term?

23 A. The term "diversion" would apply to
24 borrowing pills from a friend of family member.

25 Q. And I take it that the distributors

1 don't have the obligation to present -- prevent
2 that kind of diversion, right?

3 MS. DICKINSON: Objection to form.

4 A. No. I think that a prudent
5 distributor of narcotics can have an impact on
6 reducing the possibility of that type of diversion
7 as well.

8 Q. A distributor couldn't control drugs
9 once they're in somebody's medicine cabinet,
10 right?

11 A. Staff person for McKesson can't go
12 into someone's home and prevent them from sharing
13 pills, but when you have a very aggressive
14 prescriber of opioids who is prescribing far more
15 than necessary and you're putting all of these
16 excess pills in someone's home, you're increasing
17 the opportunity for diversion and a distributor
18 can absolutely request from a pharmacy that's an
19 outlier who are the doctors writing these
20 aggressive prescriptions and explain to that
21 pharmacy that we will not continue to supply you
22 if you're going to fill prescriptions for these
23 very aggressive prescribers and by doing so, we'll
24 be able to limit the -- that type of diversion
25 that you're asking me about.

1 Q. But you understand there's also
2 diversion that occurs when a legitimate
3 prescription is written for a legitimate purpose
4 by a legitimate doctor, it ends up in a medicine
5 cabinet and could be diverted to family or
6 friends.

7 You agree with that?

8 MS. DICKINSON: Objection.

9 A. It can happen. But if you've got a
10 well-informed clinician, they're going to know not
11 to prescribe an opioid when an opioid isn't
12 necessary, which for much of the acute pain
13 prescribing where opioids are given out, opioids
14 are not necessary. So if you've got a
15 well-informed clinician, they're not going to give
16 an opioid if they don't have to and when they do
17 have to give an opioid, they're going to give a
18 very small amount, just enough for that patient so
19 that there shouldn't be excess pills.

20 Q. But that's a judgment the doctor
21 makes about how many pills, right?

22 MS. DICKINSON: Objection to form.

23 A. Not just a doctor, no. A pharmacist
24 who is doing their job well can call the doctor
25 and say "Did you really want to give 20 tablets of

1 Vicodin when the patient only needed two? Do you
2 want me to change this, Dr. Kolodny?" and the
3 doctor could give permission.

4 Certainly up until 2014, on
5 Hydrocodone, that could have very easily been
6 done.

7 Q. So there's two levels of diversion
8 we're talking about. One level of diversion is
9 within the closed system that you described.
10 Another level of diversion is when pills are in
11 medicine cabinets or otherwise are being
12 transferred to people without prescriptions.

13 You agree they're different?

14 MS. DICKINSON: Objection to form.

15 A. They're both -- they're both leaks in
16 the closed system. The closed system includes the
17 patient as part of that closed system and if
18 someone other than that patient takes the pill, it
19 leaked out of the closed system.

20 Q. So the closed system -- you think the
21 closed system extends to the time that a patient
22 receives the prescription and has the prescription
23 at home?

24 MS. DICKINSON: Objection to form.

25 A. I think that -- my understanding of

1 the closed system includes the patient as the end
2 user in this closed system and if that patient's
3 pills are used by somebody else, that's diversion
4 and that's where the leak occurred.

5 Q. And is it your understanding that the
6 diversion obligations of distributors extend to
7 controlling what individual patients do with
8 prescriptions?

9 A. My understanding is that a prudent
10 distributor of narcotics has the ability to
11 influence even this type of diversion that you're
12 asking me about because aggressive opioid
13 prescriber's prescriptions won't get filled if a
14 prudent distributor of narcotics is doing their
15 job well.

16 Q. There's other people who could also
17 assist with that kind of -- addressing that kind
18 of diversion; am I right? For instance, the
19 doctor or the pharmacist who limits the number of
20 pills that are being prescribed.

21 A. Absolutely the distributor is not the
22 only DEA registrant in the system that has
23 responsibilities for preventing diversion. The
24 dispenser has responsibilities to prevent
25 diversion and the prescriber has responsibilities

1 to prevent the diversion and patients, even though
2 they're not DEA registrants, have some
3 responsibilities as well.

4 Q. So in terms of looking at reasons for
5 diversion, you'd been looking at judgments made by
6 doctors, judgments made by pharmacies, judgments
7 made by patients. You're looking at reasons for
8 diversion in addition to the conduct of
9 distributors, right?

10 A. And judgments made by distributors,
11 yes.

12 Q. But you would include -- when you're
13 looking at factors that cause diversion, you would
14 look at the judgments made by doctors and the
15 judgments made by pharmacies about the decisions
16 to prescribe and the volume of pills, right?

17 A. Yes. It's a factor, but a prudent
18 distributor of narcotics could nip that in the
19 bud. It wouldn't happen. If an aggressive
20 prescriber's prescriptions can't get filled
21 because the pharmacy won't supply a -- the
22 distributor won't supply the pharmacy who is
23 filling those prescriptions, it ends there.

24 So yes, you know, the leak can happen
25 in different parts of the system, but if a

1 distributor does its job effectively, there's very
2 little leakage.

3 Q. You're saying that the distributor
4 would end up not filling orders from the
5 pharmacies, right?

6 A. So if the pharmacist does their job
7 well, they're not going to fill an inappropriate
8 prescription and if they do fill inappropriate
9 prescriptions, they're going to likely be
10 detectable if you've got a good system in place,
11 an effective system in place. So that pharmacy
12 then gets investigated or cut off and you're
13 reducing opportunities for diversion.

14 Q. So pharmacies and doctors are also
15 responsible for addressing these issues of
16 diversion in your opinion?

17 A. Yeah. There's a lot of
18 responsibility that, you know, can go around.
19 Yes, doctors need to prescribe appropriately.

20 Q. And pharmacies, in your view, also
21 need to be limiting the volume of pills and
22 prescriptions?

23 A. Pharmacists are health care
24 professionals and they're not vending machines.
25 When they see a prescription that looks

1 inappropriate, they shouldn't fill it.

2 (Whereupon, Exhibit 20 was marked for
3 identification.)

4 Q. Let me ask you to look at Exhibit 4.
5 Do we have this yet? I'm sorry. Sorry. Not 4.
6 Exhibit 20. We need to open this up.

7 THE WITNESS: Excuse me. I just
8 spilled my coffee. Can we take a break?

9 MS. DICKINSON: Why don't we take a
10 break? Let's salvage the documents. Let's
11 go off for five minutes, how about?

12 MR. HESTER: So we'll take a
13 five-minute break. So let's come back at
14 2:25.

15 MS. DICKINSON: Yes, thank you.

16 THE VIDEOGRAPHER: The time is 2:21.
17 So a three-minute break? The time is 2:21.
18 We're off the record.

19 (Recess taken)

20 THE VIDEOGRAPHER: The time is 2:31.
21 We are now back on the record.

22 Q. Dr. Kolodny, right before the break,
23 I was asking you to open up Exhibit 20. Have you
24 been able to open that up? We premarked this
25 Exhibit 20. It's a report by the Attorney General

1 of West Virginia entitled "DEA's Failure to Combat
2 Diversion Costs Lives" dated June 4, 2020.

3 Have you seen this document before?

4 A. It looks familiar.

5 Q. Let me ask you to look at the top of
6 page four of the document, please?

7 A. Okay.

8 Q. I want to ask you about the sentence
9 that begins at the very bottom of page three and
10 over to the top of four. It's a sentence that
11 reads "Of the five million Americans who reported
12 having recently abused opioids, 71% obtained those
13 drugs through diversion, not prescriptions."

14 Do you see that?

15 A. I do see that. I just want to -- if
16 you'll give me a second, I just want to read the
17 full sentence.

18 Q. Sure.

19 A. I do.

20 Q. Does that accord with your
21 understanding that of Americans who recently
22 abused opioids 71% obtained these drugs through
23 diversion, not prescriptions?

24 A. It really depends on who is misusing
25 the opioid. So for a casual non-medical user,

1 misuser, someone who reports on the National
2 Survey -- I'm assuming the source of that
3 statistic is National Survey of Drug Use and
4 Health, even though what's cited here is something
5 a little different.

6 But usually, that comes from a survey
7 question on the National Survey of Drug Use and
8 Health where people who do indicate non-medical
9 use or misuse are then asked what was the source
10 for that opioid that you misused and on that
11 survey, people answer the question -- about 71%
12 will generally say it was from a friend or family
13 who borrowed it.

14 But if you ask the question a little
15 differently or if you look at people who have
16 frequent non-medical use, for example, more than
17 150 days of the year, they used opioids
18 non-medically, in other words, people likely to be
19 addicted, the source changes and if you're looking
20 at people who are frequent non-medical users,
21 which is a proxy for being addicted to opioids,
22 the number one source is usually a doctor or a
23 drug dealer.

24 Q. That would be a doctor who is
25 prescribing illicitly? In other words,

1 prescribing more than is appropriate?

2 A. We don't know. We know that when you
3 ask people who indicate on the survey that they
4 misuse opioids frequently, more than half of the
5 year they're doing it, people, again, who are
6 likely to be addicted, you ask them "What's your
7 source," the number one source is from a
8 physician's prescription. Whether these are drug
9 dealing doctors or whether these are well-meaning
10 doctors, you can't really tell from that survey.
11 And drug dealers, I believe, are number two.

12 In other words, if you're going to
13 misuse an opioid occasionally -- and misuse
14 includes taking an opioid, borrowing somebody's
15 opioid because you have a headache. When you do
16 that, you're taking what's around, what's
17 available. Once you're hooked and you need a
18 regular supply, you can't rely on borrowing pills
19 from friends or family. You need a regular source
20 and that's where doctors and drug dealers begin to
21 play a bigger role.

22 Q. Is that scenario, the first source
23 would be doctors, second source would be --

24 MS. DICKINSON: Objection to form.

25 A. My recollection of the survey data

1 from 2015 was that, number one, I think it was --
2 actually it might have been based on 2014 data, a
3 paper by Christopher Jones -- when you look at
4 frequent non-medical users, the number one source,
5 I believe, was a physician.

6 Q. And there could be, I take it, two
7 kinds of physicians. One, a physician who is
8 legitimately prescribing, thinking it's
9 appropriate and the second kind being a physician
10 who is illegitimately prescribing, not thinking
11 it's legitimate?

12 A. Yes. And maybe a third where, you
13 know, you've got the well-meaning doctor, you've
14 got the drug dealing doctor, then there are
15 doctors who are in a gray area where they're not
16 necessarily selling a prescription to anybody who
17 walks in the door, but their prescribing practices
18 don't look all that different from the ones that
19 are selling prescriptions.

20 Q. Okay. Let me change gears to talk
21 about marketing issues.

22 First, do you have any education in
23 pharmaceutical marketing?

24 A. Yes, I do.

25 Q. What's your education in

1 pharmaceutical marketing?

2 A. So I've been researching the role of
3 marketing on the prescription opioid crisis for
4 many years, probably going back to 2006.

5 Q. So it's not a formal education, but
6 rather it's something you -- you've studied
7 pharmaceutical marketing?

8 A. That's correct. I haven't attended
9 business school for studying the marketing of
10 pharmaceutical products, but I have experience in
11 marketing pharmaceutical products.

12 Q. What experience do you have in
13 marketing pharmaceutical products?

14 A. For New York City's Health
15 Department, some of the first work I did on the
16 opioid crisis was to expand access to
17 buprenorphine treatment of opioid addiction in New
18 York City and being that we tried to increase the
19 number of doctors eligible to prescribe
20 buprenorphine and we actually conducted a Health
21 Department detailing program, very similar to the
22 type of detailing program a pharmaceutical company
23 would do where we came up with our own materials
24 and had Health Department staff, visiting doctors,
25 trying to get them to take the training and get

1 them more engaged in prescribing buprenorphine for
2 the treatment of opioid addiction. A term for
3 that might be academic detailing. So I led an
4 academic detailing campaign of a pharmaceutical
5 product.

6 Q. So you were calling on doctors to try
7 to explain the attributes and characteristics
8 of buprenorphine?

9 A. Yeah. Not myself. I led the
10 initiative. It was Health Department staff that
11 was -- visiting doctors. I gave talks on the
12 topic for medical clinics and medical groups in
13 the City. So yeah, it was individuals and it was
14 also communities and clinics that we tried to get
15 the medical community engaged in treating opioid
16 addiction with buprenorphine.

17 Q. Was the idea that by calling on the
18 doctors and explaining the attributes of the
19 products that you would be able to increase the
20 prescribing behavior by doctors?

21 A. That was part of it. But really, the
22 first thing we had to do was get them interested
23 in treating addiction and getting -- for
24 buprenorphine, you've got this barrier in that
25 doctors need to take an eight-hour class and then

1 apply to the federal government for a waiver in
2 order to treat opioid addiction with
3 buprenorphine. So we had to try to get them all
4 the way through that process so that we could
5 increase capacity for treating opioid addiction.

6 (Whereupon, Exhibit 21 was marked for
7 identification.)

8 Q. Let me ask you to look at Exhibit 21
9 in your stack. This is another one you need to
10 open. So this is a document we've premarked as
11 Exhibit 21. It's from the AMA Journal of Ethics,
12 August 2020, written by none other than Andrew
13 Kolodny, M.D.

14 I assume you are familiar with this?

15 A. Yes.

16 Q. Let me ask you to turn to page 744.
17 It's the second page of the document, I think.

18 You say, at the top of the page, the
19 first full sentence, "Opioid manufacturers
20 disseminated false claims regarding the risks and
21 benefits of opioids."

22 Do you see that?

23 A. Which page are you on?

24 Q. Second page of the document. I
25 believe it's 744.

1 A. The first full sentence starts with
2 the word "but."

3 Q. Right, right, right and I was taking
4 a -- I'm happy to read the whole thing.

5 "But the fact that opioid
6 manufacturers disseminated false claims regarding
7 the risks and benefits" -- that's what I wanted to
8 focus you on.

9 A. Yes.

10 Q. So here, you're talking about opioid
11 manufacturers that disseminated false claims
12 regarding the risks and benefits of opioids,
13 right?

14 A. That's correct.

15 Q. And what were the opioid
16 manufacturers doing to disseminate false claims
17 regarding risks and benefits?

18 MS. DICKINSON: Objection to form.

19 A. Well, the opioid industry, which
20 includes the distributors, really communicated in
21 a variety of ways to health professionals that
22 opioids are normal and acceptable for long-term
23 use for conditions where we shouldn't use them.
24 Some of the false messages were to downplay the
25 risk of addiction, to exaggerate the effectiveness

1 of long-term use, to promote the notion that there
2 should be no ceiling on the dose and you should
3 prescribe as much as people could possibly want,
4 to promote the idea that if a patient looked like
5 they were addicted, that you should -- that
6 they're probably not addicted, it's something
7 called pseudoaddiction, you should give them an
8 even higher dose.

9 There were a variety of
10 misrepresentations and these were communicated to
11 the medical community, to health professionals,
12 including pharmacists, from many different
13 avenues, from professional societies to front
14 groups to -- even government bodies that had been
15 influenced by this campaign often communicated
16 some of these messages, so that from every
17 direction, we're hearing we need to prescribe more
18 opioids.

19 Q. And your point is that it, in your
20 view, understated the risks and overstated the
21 benefits of opioids; is that right?

22 A. Yes.

23 Q. And in your letter here or in your
24 paper here, you refer to opioid manufacturers,
25 correct?

1 A. Yes.

2 Q. And then later in the same page you
3 refer to false marketing claims by opioid
4 manufacturers.

5 If you look into the third paragraph
6 under regulatory failures, you're referring to --

7 A. Yes.

8 Q. So these, again, you're referring
9 there to marketing claims by opioid manufacturers?

10 A. That is correct.

11 Q. And are those marketing claims
12 involving the risks and benefits of opioids? Is
13 that what the false marketing claims are?

14 A. Mostly, yes.

15 Q. And were those false marketing claims
16 being made to prescribers? In other words,
17 doctors and others involved in the prescribing
18 activities? Is that your point?

19 A. It represents pharmacists and nurses
20 and the public. Every possible way of influencing
21 or increasing the likelihood that a patient would
22 wind up taking an opioid was part of this
23 campaign.

24 I just want to point out that this
25 paper was published August 1st, I think, but I

1 wrote it earlier in the year and I wrote this
2 before I was aware of the role that distributors
3 were playing in promoting and marketing. That was
4 something that I've only recently learned about.

5 Q. When did you learn about activities
6 by distributors?

7 A. I began learning about their failures
8 as DEA registrants going back a while. But in
9 terms of learning that they sold a suite of
10 services to manufacturers to help them market and
11 promote opioids, that was information I learned
12 through working on the litigation and documents
13 that initially became available to me from
14 attorneys working on the case.

15 Q. So attorneys working on this
16 litigation supplied you with documents that
17 caused you to develop a view about distributor
18 marketing?

19 A. Yes, documents that really, in some
20 case, caused my jaw to drop. Because again, while
21 I had been very aware that distributors were
22 failing in their responsibilities as DEA
23 registrants and contributing substantially to the
24 opioid crisis because of that failure, I didn't --
25 I was more or less falling for the argument that

1 all the distributors do is drive the truck which I
2 knew was not a reasonable argument, but I thought,
3 you know, they supplied the pharmacies, they
4 supplied pharmacy they shouldn't supply, but I
5 didn't realize that they also promoted and
6 marketed and that was information that was made
7 available to me by attorneys working on this case.

8 Q. You said you wrote this paper earlier
9 in 2020?

10 A. Yes.

11 Q. When did you write it?

12 A. I probably began working on it maybe
13 even late 2019. Maybe December of last year,
14 January of this year.

15 Q. So this knowledge about distributor's
16 activity in relation to marketing that you're
17 referring to is information you learned in the
18 past year from reading documents?

19 A. Yes. From documents that were made
20 available to me and to -- yes.

21 Q. Before those documents were made
22 available to you, you had no knowledge about
23 distributors marketing?

24 A. Correct. I didn't know that
25 distributors promoted and marketed and advertised.

1 I didn't -- yes, that's correct.

2 Q. So in this letter, you're talking
3 only about marketing claims made by opioid
4 manufacturers, right?

5 A. So this is an article focused on the
6 FDA and its failure to properly regulate opioid
7 manufacturers, so that's what this is focused on.
8 So I don't believe it really regulates distributor
9 marketing. I could be wrong about that. But that
10 is what this -- this is focused on and so it's not
11 really so much about marketing as it is about
12 regulation of claims of safety and efficacy.

13 Q. Your point is you didn't learn
14 anything about distributor marketing related to
15 opioids until after you wrote this paper?

16 A. That's correct.

17 Q. And what you have learned came has
18 from documents that were supplied to you by
19 counsel?

20 A. And documents that I found on my own
21 going into the discovery database.

22 Q. So you went into the discovery
23 database and searched for documents?

24 A. Yes, I did.

25 Q. You had no knowledge of any of this

1 before you became an expert in the litigation?

2 MS. DICKINSON: Objection to form.

3 A. That's correct. I had no idea that
4 distributors marketed, promoted, advertised
5 opioids before the litigation.

6 Q. Let me ask you to look at Exhibit 15,
7 please.

8 A. I'm sorry?

9 Q. Exhibit 15. This one we have to
10 open.

11 A. Got it.

12 (Whereupon, Exhibit 15 was marked for
13 identification.)

14 Q. This is a document we premarked as
15 Exhibit 15. It's written by Scott Hadland and
16 others, entitled "Association of Pharmaceutical
17 Industry Marketing of Opioid Products with
18 Mortality from Opioid-Related Overdoses."

19 A. Yes.

20 Q. Have you seen this before?

21 A. I have.

22 Q. Let me ask you to look at page two,
23 please, of the document, which is -- yeah, it is
24 page two of the document.

25 A. Got it.

1 Q. Do you see the statement in the
2 middle of the second paragraph is what I wanted to
3 focus you on, under "Introduction."

4 There's a sentence that reads
5 "Direct-to-physician marketing by pharmaceutical
6 companies is widespread in the United States."

7 Do you see that?

8 A. I do.

9 Q. What's your understanding of
10 direct-to-physician marketing?

11 A. That would be communications from
12 manufacturers directly to physicians through sales
13 representatives or materials that are sent
14 directly to a physician.

15 Q. And the example you gave a few
16 minutes ago of a project you were involved in with
17 buprenorphine -- sorry, I have trouble pronouncing
18 that -- but the example you gave was a form of
19 direct-to-physician marketing, correct?

20 A. Yes, it was part of -- yes, a very
21 big part of our initiative was direct-to-physician
22 marketing. Academic detailing is the term when
23 you're not trying to make a profit off of a
24 product, but trying to improve public health.

25 Q. Is it your understanding that

1 pharmaceutical manufacturers are the entities that
2 engage in direct-to-physician marketing?

3 MS. DICKINSON: Objection to form.

4 A. I don't know whether one might
5 consider placing journal articles for physicians
6 to read direct-to-physician, so that -- or CME
7 events could, in theory, be considered direct -- I
8 guess that would be considered indirect because
9 usually there's a CME provider. But
10 direct-to-physician could include more than a
11 sales rep visiting a doctor or a material mailed
12 directly to a doctor.

13 Q. Well, let's talk about sales reps
14 calling directly on doctors to prescribe
15 particular products.

16 Am I right that that's typically
17 engaged in by pharmaceutical manufacturers?

18 A. Sometimes jointly with distributors.
19 So for example, there's evidence that I reviewed
20 from discovery indicating that -- with regard to
21 opioids -- that the campaign in the community
22 increased prescribing would involve telemarketing
23 or sales reps for the companies also visiting the
24 pharmacies while distributors are calling those
25 pharmacies or sending materials to those

1 pharmacies.

2 It's a coordinated campaign that
3 involves the distributors, not just the
4 manufacturers.

5 Q. I'm sorry. Go ahead.

6 A. To answer your question, on this
7 team, to increase prescribing, the staff for the
8 manufacturer are the ones visiting the doctor.
9 That's the role played by the staff. But on that
10 team, meaning engaged in an effort to directly
11 market to prescribers, distributors are on that
12 team.

13 Q. What I wanted to focus on is calling
14 doctors directly.

15 Is it your understanding that that's
16 done by manufacturers? Manufacturers call on
17 doctors to prescribe particular products?

18 A. So on this team, to increase the
19 sales to sell more opioids, different players on
20 the team have their role. The role of visiting
21 doctors, the staff who do that, they work for the
22 manufacturer.

23 Q. And is it that staff that is
24 responsible for describing the attributes and
25 characteristics of the product to individual

1 doctors?

2 MS. DICKINSON: Objection to form.

3 A. The player on this team to increase
4 sales that talks to the doctors and promotes the
5 product directly in a conversation with the
6 doctor, that would be a staff person working for a
7 manufacturer.

8 Q. Am I right that in the industry
9 manufacturers are the ones who provide the
10 information to individual doctors about the
11 attributes and characteristics of particular
12 drugs?

13 MS. DICKINSON: Objection to form.

14 A. Manufacturers can do that directly
15 through sales reps or those messages can be
16 communicated indirectly to prescribers through a
17 variety of mechanisms that in some cases involve
18 distributors, like distributors running services
19 to publish journal articles that a doctor wants to
20 read that can have deceptive information in them.
21 But the visiting of the doctor -- again, the
22 marketing to the doctor involves more than just a
23 sales rep visiting that doctor. Much more.

24 But when we're talking about somebody
25 visiting that doctor in their office, that role is

1 played by somebody who works for a manufacturer.

2 Q. And it's the manufacturer or their
3 representatives that provide the specific
4 information to the doctor about the risks and
5 benefits of particular drugs, correct?

6 MS. DICKINSON: Objection to form.

7 A. If we're talking about one way in
8 which there is marketing to doctors, that way that
9 it involves a sales rep visiting the doctor, yes,
10 but there are other ways of communicating
11 misinformation about opioids to prescribers that
12 are not necessarily a manufacturer, but are
13 actually a distributor.

14 Q. The information that was developed
15 about the risks and benefits of opioids through
16 clinical study, that was developed by
17 manufacturers, right?

18 MS. DICKINSON: Objection to form.

19 A. I'm sorry. Could you ask that
20 question one more time please?

21 Q. Yes. I didn't ask it that well.

22 The information that was developed
23 about the addictive properties and the risks and
24 benefits of opioids was developed by manufacturers
25 through clinical trials, correct?

1 A. Not really. What we know about the
2 addictive nature of opioids, what really -- what
3 we -- the scientific understanding about opioids,
4 their risks and benefits, hasn't really come from
5 the clinical trials that were conducted by drug
6 companies. It's come from medical research going
7 back decades.

8 Q. So if you look back at your Exhibit
9 21, which is the paper you wrote, if you look at
10 the second page, 744, where you refer to false
11 claims regarding the risks and benefits of
12 opioid -- sorry, I don't mean to rush you.

13 A. I found it. Okay. I got it.

14 Q. I'm on that second page again. It's
15 744.

16 Where you refer to false claims
17 regarding the risks and benefits of opioids, I
18 take it that information had to be developed on
19 the risks and benefits of opioids? Somebody
20 developed a body of knowledge? Whether it was
21 correct knowledge or incorrect knowledge, somebody
22 developed a body of knowledge on that, right?

23 A. Not really.

24 Q. How did they disseminate false claims
25 regarding the risks and benefits? Did they have

1 any data to support it?

2 MS. DICKINSON: Objection to form.

3 A. In many cases, no, that's --

4 Q. Let me take you back to the
5 discussion about Purdue. Let's look at the bottom
6 of 744 and the top of 745.

7 There's a reference at the very
8 bottom of 744 to the label on oxycodone that had a
9 broad indication, allowing Purdue to promote the
10 drugs used for common conditions. Do you see
11 that? Purdue developed the claims for the label
12 for Oxycontin, right?

13 MS. DICKINSON: Objection to form.

14 A. Purdue wrote the label and it was
15 ultimately approved by FDA. It would be changed
16 many times over the years, but Purdue wrote that
17 label. That's correct.

18 Q. And then that label then became the
19 basis for claims about the risks and benefits of
20 opioids, right?

21 MS. DICKINSON: Objection to form.

22 A. Some of the claims came from that
23 label, but there were false claims made or
24 misrepresentations made that were unrelated to the
25 language on the label.

1 Q. That was conduct that Purdue engaged
2 in?

3 A. Purdue engaged in that conduct, as
4 did others and --

5 Q. Sorry. Go ahead.

6 A. Purdue did engage in that conduct, as
7 did other companies, as did third parties, as did
8 key opinion leaders, as did many well-meaning
9 clinicians and teachers who were believing these
10 messages.

11 Q. And the -- when we talk about --
12 strike that.

13 One of the points you had made is
14 your view that the medical community was misled by
15 representations about the risks and the benefits
16 of opioids.

17 Is that a fair characterization of
18 your view?

19 A. Yes.

20 Q. And in particular, individual
21 doctors, in your view, were misled about the risks
22 and benefits of opioids, right?

23 A. Yes.

24 Q. And that information about the risks
25 and the benefits of opioids was conveyed to

1 doctors through this direct-to-physician marketing
2 by manufacturers, right?

3 A. One way in which it was communicated.
4 There were many ways in which communications were
5 communicated and not just to doctors, but to the
6 medical community, including pharmacists.

7 Q. The distributors -- the customers for
8 distributors are pharmacies, right?

9 MS. DICKINSON: Objection to form.

10 A. Yes. Well, I mean customers of
11 distributors include pharmacies. Hospitals are
12 also customers of distributors. In some cases,
13 physician practices order products directly from
14 distributors, but the customers of distributors
15 include pharmacies.

16 Q. And pharmacies do not engage in
17 direct-to-physician marketing; is that right?

18 MS. DICKINSON: Objection to form.

19 A. That's a hard one. I'm not -- I'm
20 not sure. There could be some marketing to
21 prescribers by pharmacies. I'm not certain about
22 that. I'd have to think more about it.

23 Q. Distributors do not engage in
24 direct-to-physician marketing; is that right?

25 MS. DICKINSON: Objection to form.

1 A. It depends a little bit on how you
2 would define direct to physician. If you would
3 include in that definition journal articles or CME
4 events, then the answer would be yes because
5 distributors have been involved in producing
6 deceptive journal articles as well as sponsoring
7 medical education for clinicians.

8 Q. I was talking about calling directly
9 on physicians.

10 Distributors don't do that, right?

11 A. I don't believe that distributors
12 visit doctors in their offices and encourage them
13 to prescribe specific products. On the team to
14 increase sales, that position is played by
15 manufacturers.

16 Q. Let me ask you -- let's switch gears
17 a little bit.

18 Your report starts off with a
19 reference to a definition out of the restatement
20 of torts, right?

21 A. Yes, it does.

22 Q. And I take it -- again, we've
23 discussed this already -- your field of expertise
24 is not law practice?

25 A. Correct. I'm not a lawyer.

1 Q. You may be happy about that.

2 Have you read the restatement second
3 of torts or the restatement third of torts?

4 MS. DICKINSON: Objection to form.

5 A. I read the legal definition of public
6 nuisance that's in my report.

7 Q. Who supplied that to you?

8 A. Attorneys that I've been working
9 with, I asked them for that.

10 Q. Had you ever seen that definition
11 before it was supplied to you?

12 A. I'm not sure. I had an understanding
13 of public nuisance before this was supplied to me.

14 Q. I'm sorry. Go ahead.

15 A. I'm not sure if I had seen that
16 definition.

17 Q. Have you looked at any case law that
18 defines the nature of public rights for purposes
19 of evaluating a public nuisance?

20 A. I have not studied case law.

21 Q. So you haven't looked at any cases on
22 the scope of public nuisance law?

23 A. My familiarity with a particular case
24 involving application of public nuisance to opioid
25 litigation, but I haven't studied case law on this

1 topic.

2 Q. That's the Jansen case where you
3 testified as a witness?

4 A. Correct.

5 Q. Have you looked at any examples under
6 West Virginia law involving the application of
7 public nuisance to the distribution of a product?

8 A. I haven't studied cases of public
9 nuisance.

10 MR. HESTER: Okay. Let me pause for
11 a second.

12 Am I just about at five hours of my
13 time?

14 THE VIDEOGRAPHER: Yes. I wanted to
15 say, Tim, you are at four hours and 56
16 minutes.

17 MR. HESTER: How about that? That's
18 pretty good.

19 Okay. Let me just check one more
20 thing.

21 THE VIDEOGRAPHER: We'll go off the
22 record for a second?

23 MR. HESTER: Yes. Why don't we go
24 off the record for a minute?

25 Could I just consult with my

1 colleagues briefly, Dr. Kolodny? Maybe we
2 could take a five-minute break? Is that okay
3 by you?

4 MS. DICKINSON: Yes. Why don't we
5 take a break if we're going to do that?

6 MR. HESTER: Yes, let's do that.

7 MS. DICKINSON: All right. Let's
8 take five.

9 MR. HESTER: Can we come back --
10 let's come back -- we'll even be more
11 generous than five. We'll come back at 3:15.

12 Is that okay?

13 THE WITNESS: That's fine. That
14 sounds good.

15 MR. HESTER: Okay. Thank you.

16 THE VIDEOGRAPHER: The time is 3:07.
17 We are now off the record.

18 (Recess taken)

19 THE VIDEOGRAPHER: The time is 3:18.
20 We are now back on the record.

21 Q. Dr. Kolodny, are there any particular
22 false claims that were made by distributors in
23 relation to marketing of prescription opioids that
24 you have identified?

25 MS. DICKINSON: Objection to form.

1 A. Yes.

2 Q. What are those?

3 MS. DICKINSON: Objection to form.

4 A. So I'd have to go through my report
5 to come up with multiple examples, but I'll give
6 you just one example off the top of my head was
7 part of a promotion by a distributor to pharmacies
8 for a hydrocodone combination product. I think
9 this was advertising a rebate and it was for
10 hydrocodone -- a generic hydrocodone product, but
11 I guess it had a name called Stagesic and it said
12 on that promotional material "Has no street value!
13 Drug dealers and abusers don't trust capsules."

14 I've been working on the opioid
15 crisis for many years. I've treated many people
16 who are opioid addicted. The idea that by putting
17 hydrocodone in a capsule form that it has no
18 street value is just a -- totally false, but that
19 was on a communication to a pharmacy by a drug
20 distributor as part of a promotion. That's one
21 example.

22 I can actually think of some other
23 examples off the top of my head, if you'd like.

24 Q. What other ones do you have in mind?

25 A. Another example would be journal

1 articles that had misrepresentations about opioids
2 in them that overstated opioid benefits --
3 basically, exactly what we've described -- and
4 this was an article that was placed in a medical
5 journal by a subsidiary of a distributor after
6 receiving a payment from Teva Pharmaceuticals and
7 in fact, this distributor company staff
8 co-authored and were first author on that article.

9 And there are many examples of
10 distributors involvement in the normalization of
11 using opioids for conditions where we shouldn't
12 use opioids and examples of communications to
13 pharmacists that would have suggested that being
14 on opioids chronically is something appropriate.

15 Many distributors -- not many, but I
16 think all of the big three had promotions where or
17 participated in free drugs for patients where
18 there's no co-pay for opioids long term, which I
19 think sends a message that it's normal to be on
20 opioids long term and there are others like
21 patient adherence programs.

22 Patient adherence programs that
23 distributors were involved in suggest that
24 patients should be adhering to opioids long term
25 when the message for patients who are on opioids

1 is really take the lowest possibly dose for the
2 shortest period of time. The idea that a
3 distributor would promote adherence to chronic
4 opioid therapy is really sending a message of
5 normalizing a practice that's not normal. It's
6 not okay to be on opioids long term for low back
7 pain or chronic headache.

8 There are other examples, if you give
9 me a moment to -- I'm sure I can come up with
10 them.

11 Q. So let me ask you about a few of the
12 examples you gave.

13 So the journal article that you said
14 overstated the benefits or understated the
15 addiction risk, you said that was placed in a
16 journal after a payment by Teva Pharmaceuticals?

17 A. That's correct. I don't know that
18 that -- I'd have to look at that article again to
19 see if it minimized risk of addiction. It had
20 misinformation about opioids. It exaggerated
21 their benefit. It implied that -- actually, maybe
22 even explicitly stated that opioids
23 are appropriate for long term care.

24 Q. Do you know whether the content of
25 those statements -- the content in those

1 statements -- came from Teva?

2 A. Teva -- in part, Teva was -- staff
3 for Teva were a co-author of this paper. Another
4 co-author of that paper was staff for a
5 distributor.

6 Q. But do you know who supplied the
7 content about those statements on the addictive
8 risks of the opioids?

9 MS. DICKINSON: Objection.

10 A. The journal article had authors and I
11 believe the authors of the journal article are
12 responsible for the content of that article and
13 among the authors included staff for Teva, staff
14 for a distributor and an academic who works for
15 opioid manufacturers.

16 Q. When was that journal article
17 published roughly?

18 MS. DICKINSON: Objection to form.

19 A. I'd have to look. I'd rather not
20 guess. We have the article somewhere here, so ...

21 Q. So the first one that you mentioned,
22 the promotion to pharmacies for hydrocodone about
23 whether the product had street value, do you know
24 who supplied that content? Who had that content
25 that was then disseminated to the pharmacy?

1 A. I don't know. I don't know who came
2 up with that content. What I know is that a
3 distributor disseminated a blatantly false
4 statement about hydrocodone, stating it has no --
5 this particular formulation of hydrocodone has "no
6 street value!"

7 Q. Do you know what that was done,
8 roughly what year?

9 MS. DICKINSON: Objection to form.

10 A. I don't recall the date. I could
11 probably figure it out if I went through my expert
12 report.

13 Q. You mentioned the patience adherence
14 programs.

15 Do you understand that those apply
16 broadly across all prescriptions that are serviced
17 at a particular pharmacy?

18 MS. DICKINSON: Objection to form.

19 A. Yes, I do and I think for some
20 classes of drug an adherence program could
21 potentially be a thing. For example, if there are
22 patients with serious mental illness who have poor
23 adherence to their medication for schizophrenia, a
24 program that improves adherence is potentially
25 very helpful.

1 There are medical problems where if
2 patients don't adhere, they can have a serious
3 medical condition, like a stroke. So you want
4 good adherence to anti-hypertensives.

5 Opioids are not a drug that for which
6 we should have an adherence program. The message
7 that should be communicated to a patient on
8 opioids is don't take this opioid if you don't
9 absolutely need to take it, take the lowest
10 possibly dose for the shortest period of time.

11 Any kind of coaching or adherence
12 program designed to get that patient to continue
13 taking the opioid is likely to be harmful for the
14 patient.

15 Q. The adherence program only applies if
16 the patient had a prescription from a doctor,
17 right?

18 A. I would imagine so.

19 Q. Let me ask you to turn to your
20 report, page 50.

21 A. Yes.

22 Q. Here, you're discussing some lobbying
23 activities, right? Do you see this?

24 You're talking about the HDA and --

25 A. Yes.

1 Q. Have you had any involvement in
2 lobbying work yourself?

3 A. I've been involved in advocacy work,
4 which I don't think is generally considered
5 lobbying because the advocacy that I've been
6 involved in has been for federal regulation of
7 manufacturers. So I would call that advocacy, not
8 lobbying. Lobbying, I think, is when you're
9 trying to -- I think the definition would apply to
10 legislation and I think I maybe had a little bit
11 of experience with lobbying for legislation, but
12 not much.

13 Q. And you're not generally familiar
14 with the way lobbying takes place in Washington,
15 are you?

16 A. Oh, I'm very familiar with the way
17 lobbying actively takes place in Washington.

18 Q. How do you know about that?

19 A. Because I've had staff from
20 congressional offices contact me because of
21 lobbying activities. I've had actually even a
22 staff person for the DEA contact me when
23 distributors were trying to get the Insuring
24 Patient Access Act passed, the Blackburn Marino
25 bill and I've -- in terms of my work on the opioid

1 crisis and the role that the opioid industry has
2 played in trying to preserve a status quo of
3 aggressive prescribing, I've been very familiar
4 for many years with their activities, including
5 opioid distributors.

6 Q. The knowledge that you have of the
7 Pain Care Forum, where does that come from?

8 A. Some of that comes firsthand. I met
9 with the Pain Care Forum.

10 Q. You met because they wanted you to be
11 a speaker once?

12 A. No, I wanted to talk with them. I
13 was involved in an effort that I believe that
14 would result in much more cautious opioid
15 prescribing and we were at the height of opioid
16 prescribing in the United States and I was
17 concerned that the forum and its members were
18 going to try and interfere with this effort, so I
19 reached out to a Pain Care Forum member for an
20 opportunity to speak with the group.

21 I didn't think that I would be able
22 to convince all of the members of Pain Care Forum
23 to not fight against this. I thought maybe I
24 could get some to at least sit on the sidelines
25 and not work against our effort. I knew none

1 would support it. So that's why I reached out and
2 requested an opportunity to meet with the Pain
3 Care Forum.

4 Q. So you had one meeting with them?

5 A. That's correct. I had one meeting
6 with them. I was aware of them before that
7 meeting and I've certainly been aware of them
8 since.

9 Q. And how have you learned of their
10 activities?

11 A. I first learned about the Pain Care
12 Forum from federal employees who had been invited
13 to meet with the Pain Care Forum because the Pain
14 Care Forum was attempting to lobby them.

15 Q. Have you read deposition testimony or
16 documents about the Pain Care Forum?

17 A. I have.

18 Q. Do you have knowledge about the Pain
19 Care Forum based on any other interactions with
20 them aside from what you've described?

21 A. My knowledge of the Pain Care Forum,
22 besides my personal direct interaction with them,
23 comes from what I learned about the Pain Care
24 Forum through discovery documents, through
25 conversations with federal employees who met with

1 the Pain Care Forum and through the work of
2 investigative journalists on the role of the Pain
3 Care Forum, playing both on a federal and state
4 level and possibly other sources.

5 Q. Let me ask you to look at page 96 of
6 your report, please.

7 Do you have it there?

8 A. I do.

9 Q. So in the top paragraph on the page,
10 you refer to the Marino Bill.

11 Do you see that?

12 A. I do.

13 Q. Did you read the bill as it was
14 ultimately enacted?

15 A. I have read that bill.

16 Q. And have you read the amendments?

17 A. Probably. I can't remember them at
18 this point, but I believe I have.

19 Q. Do you remember when you read them?

20 A. No.

21 Q. Was it within the past year? Was it
22 for purposes of this work?

23 A. Yes. It would have been in the past
24 year that I would have looked at it.

25 Q. And you would have looked at it for

1 purposes of this expert work you're doing in the
2 litigation?

3 A. Well, I was interested in the Marino
4 Bill before there was -- before I was involved in
5 any litigation. My interests and the first time I
6 began learning about it was when I got a call from
7 a DEA staffer, who I believe at the time was
8 working in a congressional office as a liaison to
9 that congressional office, and informed me about
10 this bill and was very concerned that it could
11 pass. I didn't think it possibly could.

12 At a time when Congress was really
13 beginning to pay attention finally to the opioid
14 crisis, the idea that legislation could be
15 introduced that would weaken the DEA, I never
16 believed that could be possible. That's when I
17 first learned about it, that's when I first read
18 the bill. I think more recently, during the
19 course of my work on the litigation, I looked at
20 the legislation again.

21 Q. Okay.

22 Let me ask you about one of your
23 opinions, which is summarized, I think, at the
24 front end where you talk about the refusal of
25 defendants to take responsibility for the opioid

1 epidemic.

2 Are you generally familiar with your
3 opinions on that?

4 A. Yes.

5 Q. This idea of refusal to take
6 responsibility, would you apply that to others who
7 have been involved in the opioid epidemic?

8 MS. DICKINSON: Objection to form.

9 A. Yes, I think there are other opioid
10 industry players that haven't taken
11 responsibility. It's not just distributors.

12 Q. That would include the FDA?

13 A. It's interesting. For some of the
14 government failures, I see it a little
15 differently, but there's -- yes, I think that the
16 FDA has made mistakes that have contributed to the
17 epidemic that they haven't taken responsibility
18 for. So I do think there's a fair amount of blame
19 to go around.

20 Q. That would include DEA as another
21 player?

22 MS. DICKINSON: Objection to form.

23 A. I think that the DEA could have done
24 a better job. I don't know -- you know, if you're
25 asking me to apportion blame, that's very

1 difficult to do. I think that in terms of federal
2 agencies, I think some of the FDA's failures were
3 more significant than the DEA's failures, but both
4 in the case of DEA and FDA, it's very difficult
5 when you're a regulator with limited staff
6 regulating powerful industries.

7 In the case of the DEA, there are
8 millions of DEA registrants that they're required
9 to regulate and so I think with better funding,
10 richer staffing, the agencies may have been
11 able to -- would have been able to do a better
12 job. So I do think there's blame to go around.

13 I think one of the differences here
14 is that I wouldn't say that the FDA or DEA's
15 failures were driven by greed, which I would say
16 is true for the opioid --

17 Q. When you talk about blame going
18 around, I take it you would include manufacturers
19 of opioids as some of the players that you would
20 see as blameworthy for the opioid epidemic?

21 A. Yes. And I think the opioid
22 industry, which included -- includes distributors
23 and manufacturers.

24 Q. So you would specifically say
25 manufacturers would be one set of players that you

1 would see as worthy of blame in relation to the
2 opioid epidemic?

3 MS. DICKINSON: Objection to form.

4 A. Yes.

5 Q. Would you agree that pharmacies are
6 worthy of blame for the opioid epidemic?

7 MS. DICKINSON: Objection to form.

8 A. I think there are bad actors. There
9 were dirty pharmacies, dirty doctors and because
10 they failed or because they were greedy, many
11 people were harmed. In terms of apportioning
12 blame, I just see them as small fish. The big
13 fish were the companies that were selling millions
14 of pills, billions of MMEs, that were really
15 responsible for flooding communities with opioids
16 and that wasn't the pharmacies and/or the dirty
17 doctors.

18 Q. You speak about this idea of refusing
19 to take responsibility.

20 I take it you're not an expert in
21 corporate social responsibility, right?

22 MS. DICKINSON: Objection to form.

23 A. You know, I have an interest and I
24 think some expertise in the field of corporate
25 determinants of health, which I think ties in

1 with -- is related to the field of corporate
2 responsibility.

3 Q. But you're not an expert in corporate
4 social responsibility, are you?

5 MS. DICKINSON: Objection to form.

6 A. I have not published on that topic or
7 researched corporate responsibility. I have
8 researched the way in which corporations, through
9 their pursuit of profit, have been responsible for
10 public health catastrophe.

11 Q. So this point that you make about
12 failure to take social responsibility or personal
13 responsibility, this is based on your personal
14 view of what you think they should have done,
15 right?

16 MS. DICKINSON: Objection to form.

17 A. I'm sorry. Are you asking me what my
18 personal view is?

19 Q. No, I'm asking what's your basis for
20 saying that companies failed to take
21 responsibility for their actions? How do you form
22 your view?

23 A. Look at what happened in West
24 Virginia. Read the deposition of the mayor, the
25 fire chief or the police officer from Huntington

1 or Cabell. The devastation that occurred in these
2 communities where millions of pills flowed into
3 these communities, billions of MMEs. You have
4 corporations that reaped enormous profits while a
5 public health catastrophe was occurring in these
6 communities.

7 So that -- there's overwhelming
8 evidence that these companies could have done the
9 right thing, could have prevented this from
10 happening and instead profited enormously off of
11 what was occurring and they were aware of what was
12 happening. The whole country was aware of what
13 was happening in Appalachia with prescription
14 opioids and yet they continued to flood these
15 communities. So I don't think that -- I don't
16 think any special expertise is required to say
17 that what happened here was awful and should never
18 happen again.

19 Q. And when you say that no special
20 expertise is required, what benchmarks are you
21 looking at to decide that they should have taken
22 responsibility? What benchmarks are you applying?

23 MS. DICKINSON: Objection to form.

24 A. Death toll. I'm looking at the -- in
25 the State of West Virginia, probably tens of

1 thousands or hundreds of thousands of people
2 became addicted. I'm talking about parents who
3 lost children, children who lost parents. We have
4 testimony from, I believe, an EMS worker about
5 coming to the scene of an overdose where a child
6 was crying because the parents have overdosed and
7 the child doesn't understand what's going on.

8 There's overwhelming evidence that
9 West Virginia has suffered at the hands of these
10 corporations that could have prevented this and
11 the CEOs for the defendants in this case really
12 apologized before Congress.

13 Q. So you're reading -- you're reading
14 the deposition testimony and the CEO statements
15 and forming this view?

16 MS. DICKINSON: Objection to form.

17 Lacks foundation.

18 A. My view is, in part, informed by the
19 testimony from people in the county and from the
20 testimony of the defending CEOs and from my own
21 firsthand clinical experience, experience working
22 in West Virginia or speaking in West Virginia, my
23 research on the opioid crisis.

24 All of these factors informed my
25 opinion that the defendants in this case and that

1 the opioid industry in their pursuit of profit is
2 responsible for millions of cases of addiction and
3 thousands of deaths.

4 Q. Are you taking account also, Dr.
5 Kolodny, in your views of benefits achieved from
6 reduction of pain for people who are in pain? Do
7 you take that into account?

8 A. I appreciate the question, but
9 despite the enormous public health harms that
10 resulted from flooding communities with opioids,
11 we don't have one good piece of evidence that this
12 flood of opioids had led to improvements and
13 treatment of pain.

14 In fact, it's the opposite. We're
15 doing a worse job of treating pain by
16 overprescribing opioids. In fact, patients with
17 chronic pain have been disproportionately harmed
18 by aggressive prescribing of opioids, so you'd
19 like to think that with this enormous public
20 health price that we paid, maybe there was some
21 benefit. No evidence that I'm aware of of America
22 doing a better job of treating pain than in
23 countries where opioids are prescribed cautiously.

24 Q. Have you consulted any standards on
25 corporate social responsibility in forming your

1 views or it's really based on these judgments you
2 just described?

3 MS. DICKINSON: Objection to form.

4 A. I reviewed corporate integrity
5 statements for defendants in opioid litigation. I
6 have seen statements in some of these documents to
7 the effect that as responsible corporate citizens,
8 we don't do business with criminals. That's not
9 what I've seen.

10 I've seen that the defendants in this
11 case continued to do business with manufacturers
12 that were convicted of felonies for lying about
13 their products, continued to help them sell more
14 of their opioids. So I've seen some of these
15 documents, but I haven't really seen the companies
16 that have these documents live up to what's in
17 them.

18 Q. And that's -- I'm just trying to
19 understand the standards you're applying in
20 formulating your view that they had some
21 obligation to do more in terms of taking
22 responsibility.

23 What standards are you applying?

24 A. I think I'm applying the standard of
25 what a prudent distributor of narcotics should

1 have done.

2 Q. And where do you develop that
3 standard on prudent distributors? Where do you
4 get that?

5 A. Well, I don't think you need to take
6 a class or go to -- or earn a degree on what a
7 prudent distributor of narcotics should do.

8 Q. So when you talk about doing business
9 with companies that were cited for illegal
10 conduct -- which is another factor you mention in
11 your report, right?

12 A. Yes.

13 Q. Do you agree with me that -- I take
14 it one of the examples that you give is Purdue,
15 that pled guilty and that distributors continued
16 to work with; is that right?

17 A. That's one example.

18 Q. Teva is another?

19 A. Yes, that's another example.

20 Q. Do you agree with me that all of the
21 conduct for which they pled guilty was past
22 conduct?

23 MS. DICKINSON: Objection to form.

24 Q. In other words, at the time they pled
25 guilty, they were pleading guilty to crimes in the

1 past? Do you agree with me?

2 A. I don't see how you can plead guilty
3 to crimes you haven't yet committed.

4 Q. Yeah. Maybe it's a truism, but I
5 want you to confirm. It was past conduct that
6 they were pleading guilty to. They weren't found
7 to be engaged in a current criminal activity, were
8 they?

9 MS. DICKINSON: Objection to form.

10 A. The cases that were built up against
11 them were based on evidence of crimes that they
12 had committed I guess when files were -- as
13 they're building the case. What we do know is
14 that both in the case of Teva, which had Cephalon,
15 or Purdue, they were continuing to commit crimes,
16 even while pleading guilty to past crimes.

17 Q. But the guilty pleas that were known
18 were in relation to past activities, right?

19 A. These cases were focused on evidence
20 of crimes that had been committed in the past.

21 Q. Am I right that the DEA and the FDA
22 and the West Virginia regulators permitted these
23 manufacturers to continue to do business after
24 their guilty pleas?

25 A. I don't know. Your question suggests

1 or implies that the DEA or the FDA had the
2 authority to put them out of business after they
3 pled guilty. I'm not sure that they have that
4 legal authority to put them out of business.

5 Q. Are you unaware that they are
6 registrants under the DEA that have to have
7 continuing registration in order to continue to
8 distribute controlled substances?

9 MS. DICKINSON: Objection to form.

10 A. I understand that you -- yes, you
11 need a DEA registration.

12 Q. And if they didn't have a DEA
13 registration, they could not have continued to
14 manufacture controlled substances, right?

15 A. Yes, that's correct.

16 Q. And DEA did not withdraw their
17 registrations, did it?

18 A. I don't know that DEA would have had
19 the ability to put them out of business, out of
20 the narcotics business permanently. I don't know
21 whether or not they had the legal ability to do
22 that.

23 Q. Do you know whether the Justice
24 Department had the ability, if it so chose, to
25 require them to cease selling controlled

1 substances as a condition of their guilty pleas?

2 A. So when we talk about the DEA, I'm
3 really answering about the Department of Justice.
4 I do not know whether or not the Department of
5 Justice could have put an end to their work in the
6 narcotics business.

7 Q. Is it your understanding they
8 continued to have the authority to sell products
9 in the United States after these guilty pleas?

10 MS. DICKINSON: Objection to form.

11 A. Yes.

12 Q. You've published, Dr. Kolodny, a
13 number of papers on the opioid crisis; is that
14 right?

15 A. I have.

16 Q. And have you ever published a paper
17 stating that the distributors caused the opioid
18 crisis?

19 A. I'm not sure. I know that I
20 testified before Congress, I think in 2018 or
21 2017. In my testimony, I discussed both the
22 manufacturers and the distributors.

23 But much of my work has really
24 focused on the manufacturers because it really
25 wasn't until recently in this whole crisis that

1 the role that distributors were playing became
2 clearer.

3 Q. And in particular, when you say more
4 recently that the role became clearer with respect
5 to distributors, that's through work you did in
6 this case during 2020?

7 A. No. It became clearer when
8 investigative journalists started to publish
9 Pulitzer-winning stories about West Virginia being
10 flooded with opioids and with Congress conducting
11 an investigation, so -- and that certainly was
12 when I began to pay more attention and through my
13 work on the litigation, that's when I learned a
14 whole new role that distributors had played that I
15 had been previously unaware of.

16 Q. Let me ask you -- but going back to
17 my question about whether you published a paper
18 stating that the distributors were the cause of
19 the opioid crisis, you have not published such a
20 paper, have you?

21 A. I have never written a paper saying
22 that the distributors caused the ultimate crisis.

23 Q. If you were writing a paper about who
24 caused the opioid crisis, you would not identify
25 the distributors as the sole cause, would you?

1 A. I don't think I would write a paper
2 saying that any particular entity or party was a
3 sole cause.

4 Q. Have you done any -- have you engaged
5 in any effort to allocate the causes among
6 different sources?

7 MS. DICKINSON: Objection to form.

8 A. I haven't done research to try and
9 apportion blame, but if you ask me for my opinion
10 based on my understanding of the available
11 evidence, I believe the opioid industry, including
12 the distributors, bears the bulk of responsibility
13 for the opioid crisis, that the opioid industry
14 was really a primary substantial cause of the
15 epidemic and certainly -- I'm sorry.

16 Certainly if distributors had acted
17 appropriately, there would be no opioid crisis.
18 From day one, had the distributors told Purdue
19 they were not going to flood communities with
20 Oxycontin, from day one, had they done their job,
21 I don't believe we would have an opioid addiction
22 epidemic.

23 Q. And your view is -- when you say
24 "done their job," that would have been not selling
25 Purdue products?

1 MS. DICKINSON: Objection to form.

2 A. Certainly going back to 2003, when
3 the GAO publishes a report about how Purdue Pharma
4 is deceptively promoting Oxycontin for conditions
5 that it shouldn't have been prescribed, they could
6 have said at that point we're not going to carry
7 Oxycontin, we're not going to stock it.

8 Imagine how things would look
9 differently.

10 Q. So when you say you would assign the
11 bulk of the causation or the blame to the opioid
12 industry, that includes manufacturers as well as
13 distributors in your view?

14 A. Yes.

15 Q. And I take it you'd also assign blame
16 or causal obligations to the medical community
17 itself?

18 MS. DICKINSON: Objection to form.

19 A. That's a little trickier. I'd say
20 there are doctors who, like the corporations, were
21 driven by greed, but I think that many -- it's
22 hard to blame your average clinician who was
23 hearing from every different direction because of
24 the opioid industry's efforts that they need to be
25 prescribing much more if they're going to do the

1 right thing, that if you're an enlightened
2 clinician, you'll know that addiction is extremely
3 rare, this is the compassionate way to treat just
4 about any complaint of pain. It's hard to fault
5 the medical community when millions of dollars
6 were invested in deceiving them.

7 Q. And the medical community believed at
8 the time that it was doing the right thing?

9 MS. DICKINSON: Objection to form.

10 A. I think to this day there are many
11 aggressive prescribers who think they're doing the
12 right thing because they were deceived.

13 Q. And would you also agree with me that
14 drug cartels and criminals dealing in heroin and
15 illicit fentanyl contributed to the opioid crisis?

16 MS. DICKINSON: Objection to form.

17 A. I would say that they contributed to
18 the death toll. I think that the very sharp
19 increase in the prevalence of opioid addiction in
20 the United States and in West Virginia was really
21 driven by prescription opioids, but among people
22 with the condition of opioid addiction, illicit
23 fentanyl is responsible for a sharp increase in
24 the death toll among people who have the disease.

25 But I don't really think the cartels

1 are responsible for this sharp increase in the
2 number of people with this disease. That I
3 believe the opioid industry bears the bulk of the
4 blame.

5 Q. If you were to write a paper about
6 the opioid epidemic, I take it you would include
7 this whole mosaic that we've been talking about,
8 this whole range of factors that you would say
9 contributed to the crisis?

10 MS. DICKINSON: Objection to form.

11 A. Not necessarily. It would depend
12 what the focus of the paper was. If I'm writing a
13 paper where the focus is to critique the FDA, you
14 know, and it's going to focus on probably
15 manufacturers and what FDA could have done
16 differently, depends on what I'm focusing on.

17 MR. HESTER: Okay. Dr. Kolodny,
18 you've been very patient. Thank you. I'm
19 going to pass my time now to my colleagues.

20 Thank you.

21 MS. DICKINSON: Sara or the
22 videographer, can we get a time estimate as
23 to how much time we have left?

24 MS. McNAMARA: Let's take a break
25 now.

1 Can we go off record, please?

2 MS. DICKINSON: Sure.

3 THE VIDEOGRAPHER: The time is 3:56
4 and we're now off the record.

5 (Recess taken)

6 THE VIDEOGRAPHER: The time is
7 4:05 p.m.

8 We are back on the record.

9 EXAMINATION BY

10 MS. McNAMARA:

11 Q. Hi, Dr. Kolodny. Welcome back.

12 A. Hi there.

13 Q. My name is Colleen McNamara. I
14 represent Cardinal Health.

15 We actually had the opportunity to
16 speak a few weeks ago, right?

17 A. Yes.

18 Q. Right.

19 So in the interest of not retreading
20 the ground that Tim covered, I'm going to jump
21 around a little bit across different topics, so
22 let me know if anything is not clear as I'm moving
23 through this.

24 I first want to turn back to your
25 discussion about doctors consulting pharmacists.

1 A. Yes.

2 Q. So just so I'm clear, is it your
3 opinion that it's common for doctors to consult
4 with pharmacists about whether to prescribe an
5 opioid medication versus a non-opioid medication?

6 MS. DICKINSON: Objection to form.

7 A. I don't know that I would say that
8 it's common. I would say that clinicians
9 frequently consult pharmacists about what they're
10 going to prescribe. Whether it's a recommendation
11 for a class of drug or a specific product or a
12 dose or how the prescription is written, I believe
13 that that's very common.

14 I don't think it's common for a
15 clinician to call a pharmacist and say "Should I
16 prescribe Advil or Vicodin?" I don't think that
17 happens commonly, but I think that clinicians
18 frequently consult pharmacists.

19 Q. Okay.

20 For purposes of this deposition and
21 this case, I really want to focus on the
22 consultations about opioid prescriptions
23 specifically.

24 Would you say that doctors frequently
25 consult pharmacists about opioid prescriptions?

1 A. I would say that doctors frequently
2 consult pharmacists about what they prescribe and
3 I don't think that opioids would be -- I think
4 that opioids would be part of what they might
5 consult a pharmacist about.

6 I don't believe that because an
7 opioid is a controlled drug that would make a
8 clinician less likely to ask a pharmacist about
9 it. I think that we consult pharmacists about
10 what we prescribe and opioids are drugs that we
11 prescribe.

12 Q. Have you personally in the course of
13 your research ever attempted to quantify the
14 frequency at which doctors consult pharmacists
15 about opioid prescriptions?

16 A. No. I haven't studied that. I'm not
17 familiar with published literature on that topic.
18 I wouldn't be surprised if there is published
19 literature on doctors consulting pharmacists in
20 general. I think it's unlikely that anyone has
21 ever specifically studied opioid consultations
22 with pharmacists. I don't know.

23 But again, it is very common and I
24 think your experts will acknowledge this -- your
25 pharmacist experts will acknowledge -- that

1 pharmacists are members of a health care team and
2 that when treating a patient with regard to what
3 might be prescribed to the patient as part of
4 their treatment, it's common to consult a
5 pharmacist.

6 Q. So help me understand what "common"
7 means.

8 So out of every ten prescriptions,
9 say, how many times does a doctor call a
10 pharmacist to ask about that prescription?

11 MS. DICKINSON: Objection to form.

12 A. I don't really think it's possible to
13 come up with a number. I think it really depends.
14 If it's a medicine that the doctor prescribes
15 frequently, they know this drug, they know the
16 dose, they prescribe it a lot, they're not calling
17 a pharmacist. But if it's a medication that the
18 doctor doesn't typically prescribe, if the patient
19 comes in and says Doctor, I heard about this or
20 that drug and the doctor has never prescribed it
21 before, they might -- they might actually ask a
22 pharmacist about the drug. They might want to
23 know -- they might call the pharmacist and say
24 "Hey, do you have this in stock?" They might --
25 if the pharmacist says yes, they may say "Hey,

1 what's the starting dose on this? How is it
2 typically prescribed?"

3 I think those types of conversations
4 are common when it's a drug that a clinician
5 doesn't frequently prescribe.

6 Q. The conversation about whether a
7 medication is in stock or what the available
8 dosage is, you'd agree that those are different
9 conversations than calling up a pharmacist and
10 asking whether a particular medication is
11 appropriate to treat a particular medical
12 condition, right? Those are two different types
13 of conversations?

14 A. Different, but not that different.
15 But different.

16 Q. Okay.

17 And so you mentioned that if a
18 medication is something that a doctor frequently
19 prescribes, they wouldn't have to call a
20 pharmacist.

21 Is it also true that if a medication
22 is used to treat a common medical condition
23 suffered by 50 million Americans, say, and the
24 medication has been the subject of a lot of
25 marketing and discussion among the medical

1 community, then the doctor is unlikely to have to
2 call the pharmacist?

3 MS. DICKINSON: Objection to form.
4 Lacks foundation.

5 A. I'm sorry. Could you repeat the
6 question?

7 Q. Well, I'm going to back to your
8 testimony about -- I think you said a number of
9 times that doctors were hearing from every
10 direction that opioids are safe and effective to
11 treat chronic pain.

12 Was that your testimony, part of your
13 testimony?

14 A. Yes, that was my part of my
15 testimony.

16 Q. And do you agree that chronic
17 non-cancer pain is a condition that's suffered by
18 many millions of Americans?

19 MS. DICKINSON: Objection to form.

20 A. I think that chronic pain is very
21 frequently experienced. I pulled my hamstring.
22 If it continues to bug me, I'll meet the criteria
23 for chronic pain. It's been about two weeks.
24 It's part of being alive. We frequently
25 experience pain and millions of Americans will

1 experience chronic pain. That doesn't mean that
2 millions of patients are visiting doctors with a
3 complaint of -- tens of millions are visiting
4 doctors disabled because of chronic pain, seeking
5 medicines for chronic pain or for treatment for
6 chronic pain. Most of us grin and bear it. We'll
7 buy something over the counter. That's very
8 common.

9 Q. But in a situation where doctors are
10 hearing from every direction from across the
11 medical community that opioids are safe and
12 effective, where they perhaps are being detailed
13 by pharmaceutical companies, would you say it's
14 less likely that a doctor would have to call and
15 consult a pharmacist about an opioid medication
16 than about some other type of medication that is
17 less frequently prescribed?

18 MS. DICKINSON: Objection to form.

19 Calls for speculation.

20 A. Not necessarily. If the physician is
21 being detailed about a specific product and
22 they're being detailed effectively, they're
23 probably not going to call the pharmacist. But
24 much of what I was referring to was the unbranded
25 campaign to change the way the medical community

1 thought about opioids as a class of drug and being
2 led to believe that opioids as a class of drug
3 that rarely lead to addiction, that they're
4 appropriate for long-term use for common, chronic
5 conditions would make that doctor more apt to
6 prescribe an opioid, but not necessarily make that
7 doctor less likely to consult a pharmacist.

8 Q. So we talked about the two different
9 types of conversations, right? Are you referring
10 to not necessarily less likely to consult a
11 pharmacist about something like a dosage strength
12 or stock? That conversation might still happen,
13 right?

14 MS. DICKINSON: Objection to form.

15 A. Correct. Or -- yeah, that could
16 happen.

17 Q. But you are not able to identify for
18 me any studies or any data that quantify the
19 frequency at which doctors consult with
20 pharmacists about opioid prescriptions, correct?

21 A. I'm not aware of a study that's been
22 done on that subject. I'm aware that doctors and
23 other health care providers frequently consult
24 pharmacists. Pharmacists are seen as the experts
25 about medicines that we prescribe and I don't

1 believe that opioids are an exception to the
2 medical community frequently asking pharmacists
3 about drugs and what to prescribe.

4 And I think that your pharmacist
5 experts -- the defense experts -- would
6 acknowledge that clinicians frequently ask
7 pharmacists about medications that they prescribe.

8 Q. Can you identify a single instance in
9 Cabell County or Huntington, West Virginia where a
10 doctor consulted a pharmacist about an opioid
11 prescription?

12 A. You're asking me do I have the name
13 of a doctor or pharmacist in Cabell County where
14 this happened?

15 Q. Yes. Or any evidence that it
16 actually happened in Cabell County or in
17 Huntington, that a conversation with a pharmacist
18 influenced a doctor's decision to prescribe an
19 opioid?

20 MS. DICKINSON: Objection to form.

21 Go ahead.

22 A. I didn't see it happen, I didn't
23 listen in on a phone conversation between a doctor
24 and a pharmacist. I know that it happens
25 frequently in the United States and the last time

1 I checked, Cabell County is in the United States.
2 This is a common way that health care is practiced
3 in the United States.

4 Pharmacists are health care
5 professionals. They are members of a clinical
6 team and hospitals, they round with doctors on
7 patients. So did I witness this firsthand
8 happening in Cabell County? I didn't. Do I
9 believe -- is it my opinion that this happened in
10 Cabell County? That's my opinion.

11 Q. I know you described earlier your own
12 experience consulting pharmacists about
13 medications.

14 Did any of those consultations of
15 yours relate to opioid medications used to treat
16 pain?

17 A. I very rarely prescribe opioids for
18 the treatment of pain. I prescribe opioids for
19 treating an opioid addiction and I actually have
20 had -- so I prescribe buprenorphine for the
21 treatment of opioid addiction and I have had
22 instances where a patient might need a form of
23 buprenorphine that I don't typically prescribe
24 that's in a dose I don't typically prescribe and
25 I've had conversations with pharmacists about

1 that.

2 More often where I might consult a
3 pharmacist is if I'm prescribing a drug that I
4 don't routinely prescribe or treating a condition
5 that I don't routinely treat.

6 Like I gave as an example, this is a
7 real example of a patient with poison ivy. I
8 understand that topical steroids are appropriate
9 and would give that patient relief, but I don't
10 routinely prescribe topical steroids. If I go
11 online to try to figure out which type of topical
12 steroid, there are just tons of them and a range
13 of different potencies. I don't know which one a
14 pharmacist is even going to stock. So I would
15 call the pharmacist and I would say "I would like
16 to prescribe a mid-potency or a high-potency
17 topical steroid. What do you got?" That has
18 happened. That's happened in my clinical
19 practice.

20 Q. Understood. But again, I'm trying to
21 focus on opioid prescriptions because that's the
22 subject of this case and the subject of your
23 opinion.

24 Do you have -- what is the basis for
25 your opinion that doctors consult with pharmacists

1 about opioid medications other than your -- about
2 the treatment of -- strike that.

3 So what is the basis for your opinion
4 that doctors consult with pharmacists about
5 prescribing opioids for the treatment of pain
6 other than your own experience consulting
7 pharmacists regarding other medications or opioids
8 used to treat addiction?

9 MS. DICKINSON: Objection to form.

10 Asked and answered.

11 A. I haven't performed a survey study of
12 pharmacists or physicians to find out how often
13 you call pharmacists or ask pharmacists how often
14 you get calls from doctors. I know that it's
15 common from my own clinical experience, from
16 conversations with colleagues, from presentations
17 I've given to pharmacists about the opioid crisis
18 where pharmacists will ask questions and
19 communicate with me. I believe that it is common.
20 It is my opinion that it is common for clinicians
21 to consult pharmacists who are members of that
22 health care team about the drugs that they
23 prescribe and that opioids are not an exception.

24 Q. Okay.

25 Earlier, you testified that you

1 reviewed data from sales to pharmacies that
2 suggested diversion.

3 Do you recall discussing that?

4 A. I believe, yes.

5 Q. So outside of your work for opioid
6 plaintiff's lawyers, have you ever been asked to
7 review data showing opioid sales to pharmacies?

8 MS. DICKINSON: Objection to form.

9 A. Yes.

10 Q. In what context?

11 A. Journalists who had data that they
12 wanted to share with me data that they may have
13 obtained from a FOYA request or from an
14 investigation. So yes, I have seen data and
15 OMINUS that was presented to me from sources other
16 than attorneys.

17 Q. What journalists were those?

18 A. I believe The Washington Post reached
19 out to me about ARCOS data which they collected
20 and I believe a journalist in Poughkeepsie, New
21 York may have reached out to me about data on
22 opioid prescribing. It's difficult to remember
23 exactly.

24 Q. Approximately what year did The
25 Washington Post reach out to you about ARCOS data?

1 A. I believe 2019 when -- actually,
2 there were other journalists. I remember The
3 Washington Post, but I can't remember necessarily
4 the other outlets that had reached out to me. But
5 I think it was when ARCOS data became available
6 from the litigation.

7 Q. Was it is same time frame for the
8 Poughkeepsie journalist?

9 A. Poughkeepsie reaching out to me about
10 data that was -- I can't remember exactly what the
11 data was. I believe it involved -- it might have
12 been -- I don't remember what the data set was,
13 but that would have been a few years ago.

14 Q. Was it data relating to sales by
15 pharmaceutical distributors?

16 A. No. I don't -- it may not have been
17 distributor data.

18 Q. What year were you first retained as
19 an expert in opioid litigation?

20 A. I think it was 2018. Maybe the end
21 of 2017. I'm not exactly sure. I was helping out
22 in litigation on a voluntary basis prior to my
23 becoming an expert. The volunteer work I was
24 doing probably goes back to maybe 2013, 2014.

25 Q. Did that volunteer work relate to

1 sales by distributors to dispensers of opioids?

2 A. No.

3 Q. Prior to 2018, had you ever been
4 asked to determine whether a distributor's sales
5 were indicative of diversion?

6 MS. DICKINSON: Objection to form.

7 A. I don't think so, no.

8 Q. In preparing your report in this
9 case, what type of data did you review? Were you
10 looking at aggregate data or were you looking at
11 shipments to specific pharmacies or both?

12 MS. DICKINSON: Objection to form.

13 A. I think it was both and it was -- I
14 relied on expert reports that provided the data,
15 the tables and comments on the data.

16 Q. What standards did you apply to
17 determine whether the data suggested diversion or
18 not?

19 MS. DICKINSON: Objection to form.

20 A. I guess -- I don't know if there's a
21 name for the standard except reasonable judgment
22 that in a county in West Virginia that hundreds of
23 millions of pills -- hundreds of millions of pills
24 coming to the State of West Virginia would not --
25 would be inappropriate and so -- I don't know that

1 there are -- I consulted any published baseline on
2 what the dispensing or supplying should be, but I
3 do know based on my work on the opioid crisis on
4 opioid prescribing that products like the
5 30-milligram immediate release oxycodone -- again,
6 that's just one example -- that there's a very
7 limited appropriate use for that product and if
8 there are large numbers of dosage units of that
9 product coming into a pharmacy in Cabell County,
10 that suggests that there's a problem because the
11 genuine clinical need for a 30-milligram immediate
12 release oxycodone is extremely limited.

13 Q. So in preparing your opinions in this
14 case, were you looking at shipments by
15 distributors of oxycodone 30 milligrams to
16 specific pharmacies?

17 MS. DICKINSON: Objection to form.

18 A. If you're going to ask me questions
19 about this, I'd like to be able to review the
20 report and the tables that I looked at rather than
21 try and answer these questions based on memory.
22 My report is more than 100 pages long. I relied
23 upon multiple experts and their data sets.

24 If you're going to ask me specific
25 questions about what's in my report, I'd like an

1 opportunity to look at the sections that you're
2 asking me about.

3 Q. Well, I'm running -- I don't have
4 much time, so I'll just ask you off the top of
5 your head, do you recall as part of your analysis
6 looking at distributor shipments of oxycodone
7 30 milligrams to individual pharmacies in Cabell
8 or Huntington?

9 MS. DICKINSON: Counsel, objection.

10 I mean, he said he needs to look at
11 his report to accurately answer that
12 question.

13 Are you asking him not to look at it?
14 I mean, he just answered he needs to look at
15 it.

16 So Doctor, if you need to look at
17 your report to accurately answer the
18 question, go ahead. I understand we're
19 running short on time, but you all allocated
20 in your time in the way you desired to.

21 So Doctor, go ahead.

22 MS. McNAMARA: I'm sure you
23 understand, Ms. Dickinson, that I've gotten a
24 few pretty long speeches to very narrow
25 questions, so that is why I'm particularly

1 sensitive to time and when I rephrase my
2 question so that --

3 MS. DICKINSON: You're asking him a
4 question that's been asked a couple times
5 today and he's given you his best answers,
6 whether you like the length of not. If he
7 needs to look at his report to answer the
8 question, he needs to look at his report.

9 So Doctor, go ahead and look at your
10 report.

11 Otherwise, if you want to withdraw
12 the question, go ahead and withdraw the
13 question.

14 Q. Doctor, have you had an opportunity
15 to look at your report?

16 A. Yes.

17 Q. I'll just re-ask the question again
18 so we're on the same page.

19 In preparing your report, did you
20 look at distributor's shipments of oxycodone
21 30 milligrams to individual pharmacies within
22 Cabell or Huntington?

23 MS. DICKINSON: Objection to form.

24 A. I did.

25 Q. Earlier, when you were briefly

1 discussing the ARCOS data, I heard you say that
2 distributors had access to better data than ARCOS
3 through IQVIA and IMS Health.

4 Did I hear that correctly?

5 A. Yes. More detailed data, prescriber
6 data.

7 Q. Got it.

8 Okay.

9 So what specific data could
10 distributors purchased from IQVIA or IMS Health
11 that was better than ARCOS?

12 A. The same data the manufacturers were
13 purchasing. So that if a distributor had wanted,
14 they could purchase IQVIA data and they would be
15 able to see within a community who the outlier
16 prescribers are and could have communicated to the
17 pharmacies in the county that if you dispense
18 prescriptions written by these aggressive
19 prescribers, we will not continue to supply you
20 with narcotics.

21 So very detailed information, the
22 same information that manufacturers use to figure
23 out which doctors they're going to detail, the
24 same data that they use to figure out how to
25 compensate sales reps for getting a prescriber to

1 prescribe more, that data could have been
2 purchased by the defendants in this case.

3 Q. Have you personally ever looked at
4 that data that's available for purchase from IQVIA
5 or IMS Health?

6 A. I have.

7 Q. When did you do that?

8 A. In the course of work on litigation
9 work, documents that were obtained from discovery
10 or data that was requested, so I've seen the data
11 that was available.

12 Q. Have you reviewed the data that was
13 available at different points in time or did you
14 just review, like, a single snapshot of it?

15 MS. DICKINSON: Objection to form.

16 A. I believe I reviewed snapshots. I
17 don't think I've seen IQVIA data trended, so it
18 would have been snapshots. It could have been
19 data that covered a period of time cumulative, but
20 it wasn't trended out.

21 Q. What was the earliest version of
22 IQVIA or IMS data you that you recall looking at?

23 A. I don't recall it. I don't recall
24 the date of the data that I was looking at. I
25 would have been looking at that data probably in

1 2019, maybe 2018 would have been the first time I
2 would have been looking at IQVIA data firsthand.

3 I'm certainly familiar with studies
4 that have been published using IQVIA data and have
5 done research using PDMP data and understand some
6 of the differences between what's available from
7 PDMP data and what's available from IQVIA data and
8 there are limitations to both.

9 Q. What are the limitations to IQVIA
10 data?

11 A. IQVIA data doesn't include 100% of
12 pharmacies, so IQVIA data is collected from
13 pharmacies that I believe agree to sell their data
14 to IQVIA and not every pharmacy will participate
15 in that.

16 For the pharmacies that do
17 participate, it's very good data and where data
18 from IQVIA indicates a doctor may be a very
19 aggressive prescriber, motivation by not all
20 pharmacies participating would, if anything, just
21 maybe give -- minimize how aggressive that
22 particular prescriber is if you don't have all of
23 pharmacies, but with the pharmacies is that do
24 participate -- and I think it's upward of 80% of
25 pharmacies nationally that participate -- the pill

1 mills can be spotted.

2 Q. Have you ever done any research of
3 your own that involved spotting those pill mills
4 using IQVIA data?

5 A. I've done some work and I'm familiar
6 with research that involves identifying doctors
7 likely to be operating pill mills through PDMP
8 data, not IQVIA data. IQVIA data is generally
9 purchased by industry. It's very expensive for
10 researchers to access it. I've reached out to
11 IQVIA for their data and it was very expensive.

12 Q. And distributors don't have access to
13 PDMP data, correct?

14 A. Not necessarily. PDMP data can be
15 made available and identified. PDMP data in some
16 states can be FOYA'd, so certainly if a
17 distributor reached out to a state bureau of
18 narcotic enforcement and said "Hey, can we
19 collaborate on identifying pill mills?" I think
20 that could have happened.

21 Q. So can PDMP data be FOYA'd in West
22 Virginia?

23 A. I don't know.

24 Q. What is your basis for believing that
25 if distributors had reached out to the State of

1 West Virginia that the State of West Virginia
2 would have handed over some form of its PDMP data?

3 MS. DICKINSON: Objection to form.
4 Lacks foundation.

5 A. I don't know. I believe that a state
6 bureau of narcotic enforcement and a prudent
7 distributor of narcotics could be working together
8 collaboratively so as to address a public health
9 catastrophe happening in the State of West
10 Virginia. So I don't know for certain, but I
11 believe that they could have worked together to
12 address this.

13 Q. And that's just based on your belief,
14 right? Not based on any evidence you've seen of
15 West Virginia being willing to turn over PDMP data
16 to distributors?

17 A. I'm saying that I believe it was
18 feasible that they could have worked together and
19 that a distributor that really wanted to ensure
20 that its products weren't getting diverted, that
21 recognized that there are communities in West
22 Virginia that have been devastated, that there's
23 been a massive loss of life, I want to do
24 everything I can to make sure that no pills are
25 diverted, that there's a lot a distributor could

1 have done from purchasing IQVIA data and telling
2 every pharmacy in the state "Do not fill
3 prescriptions written by these doctors" to
4 reaching out and working collaboratively with law
5 enforcement.

6 Q. Do you know whether distributors ever
7 asked DEA to provide the identified ARCOS data to
8 help them in their anti-diversion efforts?

9 A. I'm aware that distributors have made
10 a case that the DEA should have shared more
11 information with them and if the DEA had shared
12 more information with them, they would have been
13 able to prevent diversion, that they weren't able
14 to get data on what other distributors were
15 supplying and have attempted, I think, to shift
16 blame for their failures to the DEA and that's one
17 of the arguments -- I think a bogus argument --
18 that they make.

19 Q. I think my question was a little
20 different and maybe a little narrower.

21 Do you know whether distributors
22 actually asked DEA to provide them with the
23 identified ARCOS data?

24 A. I believe that distributors asked the
25 DEA -- have complained that the DEA has not given

1 them ARCOS data that could be helpful to them in
2 preventing diversion. I've heard them make that
3 argument.

4 Q. Do you know whether they asked?

5 A. They're making the argument -- I
6 think they made the argument that they wanted it
7 from the DEA and the DEA didn't give it to them.

8 Q. Okay.

9 And does that indicate to you that
10 they asked and DEA said no?

11 MS. DICKINSON: Objection to form.

12 Calls for speculation.

13 A. No. It indicates to me that they're
14 attempting to shift blame and, as I mentioned, I
15 think it's a bogus argument. They didn't need --
16 if they had just worried about themselves, if they
17 had not shipped orders that were suspicious, if
18 they had stopped supplying outlier pharmacies, we
19 could prevented diversion.

20 If they had called their distributor
21 colleagues from the other companies and said "Hey,
22 we just stopped shipping to this pharmacy because
23 it's a dirty pharmacy, you shouldn't ship to them
24 either," we could have put those pharmacies out of
25 business.

1 Q. There's a medical board in West
2 Virginia, correct?

3 A. Yes.

4 Q. Are you aware of any evidence that
5 any of the distributors' customers were filling
6 prescriptions for doctors who are not licensed by
7 the State of West Virginia Medical Board?

8 MS. DICKINSON: Objection to form.

9 A. I'm sorry. Can you ask that again?

10 Q. Yeah, sure.

11 Are you aware of any evidence showing
12 that distributors' customers were filling
13 prescriptions written by doctors who were not
14 licensed by the State of West Virginia?

15 A. I don't know if that happened. It
16 could have -- I'm not aware of evidence that said
17 prescriptions were filled by doctors that didn't
18 have a license or DEA registration.

19 Q. I'd like to turn to the distributor
20 marketing services for a few minutes.

21 Now, you understand that the
22 marketing services offered by distributors were
23 not just limited to opioids, right?

24 A. Yes.

25 Q. Do you know what percentage of the

1 marketing services provided by Cardinal Health
2 went towards opioid products as opposed to
3 non-opioid products?

4 A. No.

5 Q. Do you know that for either McKesson
6 or ABDC?

7 A. I don't know what percentage, but the
8 percentage wouldn't affect my opinion that it's
9 inappropriate.

10 Q. Approximately how many instances did
11 you see in your review of thousands of documents
12 of Cardinal Health marketing opioids?

13 MS. DICKINSON: Objection to form.

14 A. You're asking me how many documents I
15 saw out of the thousands?

16 Q. Yes.

17 How many instances did you see of
18 Cardinal Health marketing an opioid product?

19 MS. DICKINSON: Objection to form.

20 A. I can't really remember how many
21 examples. I saw multiple examples, but how many,
22 I didn't count and even if I had counted, I don't
23 know that I'd be able to remember.

24 Q. Did you cite them in your report?

25 MS. DICKINSON: Objection to form.

1 A. I did cite in my report, I believe,
2 examples of Cardinal Health promoting and
3 marketing opioids, yes.

4 Q. Okay.

5 Among the number of boxes that you
6 received, did you receive one of them that had a
7 set of documents starting with CAH?

8 A. I believe I did. Should I --

9 Q. Yes, please.

10 MS. DICKINSON: Just while he's
11 looking for that, from the videographer, how
12 much more time do we have?

13 THE VIDEOGRAPHER: We are at six
14 hours and 13 minutes.

15 MS. DICKINSON: Okay.

16 MS. McNAMARA: So can you pull out
17 the document called CAH Exhibit 4? I marked
18 this on Exhibit Share as Exhibit 22.

19 (Whereupon, Exhibit 22 was marked for
20 identification.)

21 MS. DICKINSON: Dr. Kolodny, don't
22 hurt yourself. That looks a little scary
23 with those scissors.

24 THE WITNESS: Got it.

25 Q. All right. Great.

1 Does the document in front of you
2 have the Bates label in the lower right-hand
3 corner ending in 133350?

4 A. Yes.

5 Q. Okay. Great.

6 So Exhibit 22 is an email with an
7 attached service flash from Cardinal Health.

8 Is that correct?

9 A. Yes.

10 Q. This service flash in Exhibit 22 is
11 an announcement of some new items, correct?

12 A. Yes.

13 Q. And is this an example of a
14 distributor marketing, advertising or promoting
15 opioids as you've been referring to it today?

16 MS. DICKINSON: Objection to form.

17 A. Yes.

18 Q. Now, one of the products in this
19 announcement is a fentanyl sublingual tablet.

20 Do you see that?

21 A. I do.

22 Q. And that's an opioid product,
23 correct?

24 A. An exceptionally dangerous opioid
25 product with an exceptionally limited indication.

1 Q. If you look at the document, next to
2 the Abstral logo on the right; there's a heading
3 that says "Introducing Abstral from Galena."

4 Do you see that?

5 A. I do.

6 Q. On the second line, about halfway
7 over, it says that -- I'll read from the document
8 -- "Abstral is an opioid agonist indicated for the
9 management of breakthrough pain in cancer patients
10 18 years of age and older who are already
11 receiving and who are tolerant to opioid therapy
12 for their underlying persistent cancer pain."

13 Did I read that correctly?

14 A. You read that correctly.

15 Q. Is that the very narrow indication
16 that you're referring to?

17 A. It is.

18 Q. And then below the ordering
19 information, the document notes that Abstral
20 carries a black box warning.

21 Do you see that?

22 A. I do.

23 Q. In your view, is there anything false
24 or deceptive about the information provided here
25 about Abstral?

1 A. No, not on this particular promotion.
2 On Cardinal Health promotions that I can give you
3 as examples, there is deceptive information. This
4 is -- what's listed here is not deceptive. It
5 looks it's -- like they're printing the FDA
6 indication.

7 Q. And in your opinion, is it
8 inappropriate for a distributor to send a
9 notification like this that contains information
10 about the indication of the product?

11 A. Yes.

12 Q. Why is that?

13 A. Because I don't believe that opioid
14 distributors should have been helping promote
15 opioids, particularly when we couldn't handle the
16 opioids that we already have in the United States.
17 There's an oversupply of opioids. Your client is
18 getting paid to send out this announcement for a
19 reason. The reason is that the manufacturer --
20 Abstral believes it will make more money if
21 pharmacists or pharmacies see this promotion and
22 then stop the drug.

23 And what generally would happen,
24 based on knowledge I learned through reviewing
25 discovery, is that this isn't done in a vacuum.

1 That while this service flash is being sent by
2 your client to pharmacies, sales reps are visiting
3 doctors in these communities. The idea being that
4 whether a doctor writes a prescription for Abstral
5 that the pharmacy will have it because if the
6 patient gets to the pharmacy and they don't have
7 Abstral, the patient could wind up getting a
8 different product, maybe not even an opioid, maybe
9 not such a dangerous opioid.

10 And what we do know is that even
11 though the indication here is the FDA indication,
12 we know that when you look at the patients that
13 wound up getting transmucosal fentanyl products, a
14 very tiny sliver of those patients actually were
15 patients with cancer who had breakthrough pain and
16 were already opioid tolerant. The large majority
17 of the patients who received this class of drug
18 were patients who didn't even have cancer and
19 that's why the products were being promoted.

20 So this is part of an overall
21 campaign for the manufacturer and the distributor
22 to make money off of an extremely dangerous
23 opioid. It shouldn't have happened and there are
24 points at which distributors, based on
25 communications I've seen in the discovery, where

1 it's clear that the distributors recognized they
2 shouldn't be doing this anymore.

3 So yes, I think this is
4 inappropriate. They should not be promoting
5 opioids.

6 Q. Have you attempted to quantify or
7 otherwise evaluate the impact of distributors
8 marketing to pharmacies purchases of opioid
9 products?

10 MS. DICKINSON: Objection to form.

11 A. So I have very good evidence that
12 these promotions were effective because
13 manufacturers continued paying distributors to do
14 this. If it didn't work, if it didn't make more
15 money for the manufacturers and the distributors,
16 it would have stopped.

17 So there's very good evidence that
18 this did increase sales of opioids in the United
19 States, in West Virginia, in Cabell County at a
20 time when we couldn't handle the opioids that we
21 already had.

22 Q. And as I understand it, as you just
23 described it, the evidence is the manufacturers
24 kept paying for this service?

25 MS. DICKINSON: Objection to form.

1 Lacks foundation.

2 A. Yes. The good evidence that these
3 advertisements, that these promotions, worked is
4 that they just kept happening and happening and
5 happening.

6 Q. Have you ever looked at the effect on
7 purchases by the pharmacies or distributor sales
8 to the pharmacies before and after these marketing
9 materials were sent to the pharmacies to determine
10 their impact?

11 A. I am aware -- I think I cite in my
12 report evidence that these were effective. I
13 think there's communication cited in my report of
14 a distributor -- I believe communicating to
15 Purdue -- on how effective one of these promotions
16 were.

17 I think it might have been a patient
18 adherence program -- maybe for the Butrans
19 patch -- where this type of marketing activity
20 that a service sold by a distributor had an
21 increase, had a positive impact on sales of that
22 opioid. So there is some data out there, some of
23 which I've cited in my report.

24 Q. You have not done that analysis
25 yourself, correct?

1 A. These were analyses, I believe, that
2 were done by manufacturers and/or distributors to
3 show that this works.

4 Q. And you've identified one to me right
5 now.

6 Was that one that you described an
7 analysis of Cabell County or Huntington, West
8 Virginia?

9 MS. DICKINSON: Objection to form.

10 A. I don't believe it was. I think it
11 was national data is my understanding, but the
12 last time I checked, Cabell County is in the
13 United States.

14 Q. Have you seen any evidence showing
15 that any of these marketing materials were
16 actually disseminated to any pharmacies in Cabell
17 County or West Virginia? Have you seen the
18 transmissions to the pharmacies?

19 MS. DICKINSON: Objection to form.

20 A. I have seen samples of what was
21 transmitted. Many of these promotions are done
22 over the internet, like glimmer buttons or pop ups
23 if you use the right search term. And the last
24 time I checked, Cabell County uses the same
25 internet that the rest of the United States uses,

1 so I have every reason to believe these were
2 promotions were disseminated in Cabell County.

3 Q. You can't point to any evidence that
4 any pharmacist in Cabell County or Huntington ever
5 received or considered these materials in deciding
6 whether to purchase, correct?

7 MS. DICKINSON: Objection to form.

8 Lacks foundation.

9 A. So some of these promotions ran on
10 the order systems that the defendants operated and
11 so if you were a pharmacy in Cabell County and a
12 customer of one of the defendants, to order their
13 products would have required you to use their
14 ordering system where you would have been exposed
15 to these promotions. So it doesn't make sense to
16 me that there would have been some firewall around
17 Cabell County that it wouldn't have seen these
18 promotions.

19 Q. But you haven't seen any evidence
20 indicating that these promotions had any influence
21 on purchasing decisions in Cabell County or
22 Huntington, correct?

23 MS. DICKINSON: Objection to form.

24 Asked and answered.

25 A. I've seen evidence that it had an

1 impact. I believe that was national data and the
2 last time I checked, Cabell County is in the
3 United States.

4 Q. And you have not conducted any survey
5 or some other study of whether pharmacists
6 consider these types of materials in deciding
7 whether or not to purchase, correct?

8 MS. DICKINSON: Objection to form.

9 A. It wouldn't influence my opinion,
10 even if there was a survey of pharmacists saying
11 this doesn't affect them because many targets of
12 marketing don't recognize that they're marketing.
13 If you ask physicians whether or not a sales rep
14 detailing them on a pharmaceutical product
15 influences their prescribing, many physicians will
16 say it has no influence on what I do, maybe it
17 influences my colleagues, but not me.

18 But of course it does have an
19 influence because that's why drug companies keep
20 sending sales reps to doctors. They know that it
21 works. The evidence that it works is that your
22 client and the defendants in this case continued
23 to sell these services to manufacturers.

24 Q. The distributor defendants in this
25 case submitted ARCOS data to DEA throughout the

1 relevant time period for this litigation, correct?

2 MS. DICKINSON: Objection to form.

3 A. I believe that's correct.

4 Q. So DEA always had data showing which
5 pharmacies each distributor was shipping to and
6 the quantity that was being shipped, correct?

7 MS. DICKINSON: Objection to form.

8 Lacks foundation.

9 A. I believe that the DEA had access to
10 shipment data.

11 MS. McNAMARA: Can we take a short
12 break?

13 MS. DICKINSON: Sure.

14 MS. McNAMARA: I'm done. I'm going
15 to pass.

16 MS. DICKINSON: Okay. All right.

17 MS. McNAMARA: Thank you, Dr.
18 Kolodny.

19 MS. DICKINSON: Why don't we take
20 less than five minutes or just five minutes,
21 Dr. Kolodny, because I think we only have 20
22 minutes or so --

23 MS. McNAMARA: Can we go off the
24 record, please?

25 MS. DICKINSON: Sure.

1 THE VIDEOGRAPHER: The time is
2 4:57 p.m. and we are now off the record.

3 (Recess taken)

4 THE VIDEOGRAPHER: The time is 5:04
5 p.m. We are now back on the record.

6 EXAMINATION BY

7 MS. VITALE:

8 Q. Good afternoon, Dr. Kolodny. This is
9 Christina Vitals and I represent defendants
10 AmerisourceBergen Drug Corporation or ABDC.

11 A. Hi there.

12 Q. So I wanted to follow up on something
13 you said with prior counsel regarding the fact
14 sheet that you just covered.

15 You said "These things are not done
16 in a vacuum. When the doctor writes a
17 prescription for Abstral, the pharmacy may not
18 have it. If the pharmacy doesn't have it, the
19 patient could end up getting a different product."

20 Do you remember that testimony you
21 just gave?

22 A. I do.

23 Q. Could you go to ABDC document tab 32?
24 It should be in one of smaller boxes.

25 A. Which exhibit?

1 Q. ABDC 32. I'm going to mark this on
2 the record as ABDC 23.

3 A. Okay.

4 (Whereupon, Exhibit 23 was marked for
5 identification.)

6 Q. Great. You will see this is West
7 Virginia Code Section 30-5-12b. It states
8 "Equivalent means drugs or drug products which are
9 the same amounts of identical active ingredients
10 and same dosage form and which will provide the
11 same therapeutic efficacy and toxicity if
12 administered to an individual and is approved by
13 the United States Food and Drug Administration."

14 That was Section 6.

15 Did I read that correctly?

16 A. Yes.

17 Q. Then if you go down to the paragraph
18 below that's b, it says "A pharmacist who receives
19 a prescription for a brand name drug or drug
20 product shall substitute a less expensive
21 equivalent generic name drug or drug product
22 unless in the exercise of his or her professional
23 judgment, the pharmacist believes that the less
24 expensive drug is not suitable for the particular
25 patient. Provided that a substitution may not be

1 made by the pharmacist where the prescribing
2 practitioner indicates that in his or her
3 professional judgment, a specific brand name drug
4 is medically necessary for a particular patient."

5 Did I read that correctly?

6 A. Yes.

7 Q. I'm sorry. Was that a yes?

8 A. That was yes.

9 Q. So in fact, the patient could not end
10 up getting a different product, but can only get
11 an equivalent product as prescribed by the West
12 Virginia code; isn't that accurate?

13 MS. DICKINSON: Objection to form.

14 Lacks foundation.

15 Calls for a legal conclusion.

16 Go ahead and answer if you can,

17 Doctor.

18 A. No, it's not accurate.

19 Q. And why is it not accurate?

20 A. You're referring to my prior
21 testimony with regard to Abstral. I don't believe
22 that there is an equivalent product to Abstral.

23 Q. Right.

24 So then the patient could not get a
25 different product without the prescriber being

1 contacted and writing a different prescription,
2 correct?

3 MS. DICKINSON: Objection to form.

4 A. No, not necessarily correct.

5 Q. So you're saying the pharmacist could
6 substitute his own judgment for a patient he's
7 never seen or medical records that he's never
8 reviewed and give the patient a different product?

9 MS. DICKINSON: Objection to form.

10 Lacks foundation.

11 Compound.

12 A. No, that's not what I'm saying.

13 Q. So what are you saying?

14 MS. DICKINSON: Objection to form.

15 A. I'm saying that if the pharmacy
16 didn't have Abstral, there's a good chance that
17 the patient would have walked out of that pharmacy
18 without receiving a prescription for a
19 transmucosal fentanyl product that potentially
20 would have saved that patient's life because these
21 are exceptionally dangerous -- that were
22 overwhelmingly prescribed to patients who should
23 not have received them.

24 So a promotion that increases the
25 likelihood that the pharmacy will stock Abstral is

1 a promotion that also includes the likelihood that
2 the patient will receive Abstral, which is the
3 intent, which is why the manufacturer of Abstral
4 is paying the distributor to promote the drug.

5 Q. So you were not saying before that
6 the pharmacist could substitute a different drug?

7 MS. DICKINSON: Objection to form.

8 A. No, I was saying that the patient
9 might not get that drug.

10 Q. Thank you.

11 All right. You can put that aside.

12 You state that in your report
13 defendants, and ABDC in particular, used "various
14 marketing tools to promote opioid analgesics and
15 the revisionist message of liberalized prescribed
16 that fostered sales and addiction."

17 Correct?

18 A. Correct.

19 Q. And one example for your claim that
20 distributors sold services to increase the demand
21 of opioids that you cite is ABDC "placing in
22 pharmacy digital advertisements to appeal to
23 customers."

24 Correct?

25 MS. DICKINSON: Counsel, what page

1 are you at?

2 MS. VITALE: Page 15 of his report.

3 MS. DICKINSON: Okay. Thanks.

4 Q. Did I state that correctly?

5 A. Let me --

6 MS. DICKINSON: You've got to give
7 him a minute to get there.

8 MS. VITALE: Sure.

9 A. You're on page 15 of my report?

10 Q. Correct.

11 A. Where on the page?

12 Q. Second paragraph, it starts with as
13 "As a result of these activities ..." Go to the
14 last sentence. So I'll state it again.

15 You state in your report that
16 distributors sold services to increase the demand
17 of opioids and one of the examples you gave is
18 ABDC placing in-pharmacy digital advertisements to
19 appeal to customers.

20 Is that correct?

21 A. That is correct. I believe that's
22 correct. I'm just not following where you are on
23 the report.

24 MS. DICKINSON: I'm not seeing it
25 either. I'm sorry, Christina. Can you check

1 your page number? I don't think you're
2 reading from the right page.

3 MS. VITALE: Sorry. Page 14. My
4 apologies.

5 A. Okay. I see the paragraph that
6 begins "As a result ..."

7 Q. Okay.

8 The customers that you're referring
9 to here are licensed pharmacies and pharmacists?

10 MS. DICKINSON: Objection to form.

11 Where? Referring to where?

12 Q. In the sentence that says "Placing
13 in-pharmacy digital advertisements to appeal to
14 customers," the customers you're referring to in
15 the last sentence in the second paragraph on page
16 14 of your report are licensed pharmacies and
17 pharmacists, correct?

18 A. The last sentence? The sentence that
19 begins "Distributors did more than simply ship
20 orders ..."?

21 Q. Correct.

22 Are the customers that you're
23 referring to in the last sentences that you
24 literally end the paragraph with, are those
25 licenses pharmacies and pharmacists?

1 A. They include licensed pharmacies and
2 pharmacists.

3 Q. So you're saying that digital
4 advertisements are going to other customers that
5 are not pharmacies or licensed pharmacists with
6 this sentence?

7 A. I believe that customers of
8 distributors were not limited to pharmacies, that
9 there were other customers. In some cases,
10 clinics purchased drugs directly from distributors
11 and hospitals, so I would say that it includes
12 pharmacies and pharmacists, but may include other
13 customers.

14 Q. Okay.

15 And you cite the glimmer button.
16 You've cited that today in your testimony on
17 Bergen's Accusource computer program.

18 That would be an example in your mind
19 of these placing in-pharmacy digital
20 advertisements to appeal to customers, correct?

21 A. Yes, that's an example.

22 MS. VITALE: Can you go to ABDC tab
23 three? I'm going to mark this as ABDC
24 Exhibit 24.

25 THE WITNESS: Got it.

1 (Whereupon, Exhibit 24 was marked for
2 identification.)

3 Q. This document states "During the
4 month of January, we will have a glimmer button on
5 Bergen's Accusource system. This glimmer button
6 will show up when a pharmacist calls for a
7 targeted competitor. Pushing the button will then
8 reveal information on Oxycontin to the
9 pharmacist."

10 Did I read that correctly?

11 A. Yes.

12 Q. It goes on to say "During January, we
13 have targeted 25 competitors, including Vicodin"
14 and then it lists the 24 other drugs.

15 A. Yes.

16 Q. Did I read that correctly?

17 A. Yes.

18 Q. Okay.

19 Is Vicodin an opioid?

20 A. It is.

21 Q. Is Percocet an opioid?

22 A. It is.

23 Q. Is Duragesic an opioid?

24 A. Yes.

25 Q. Is MS Contin an opioid?

1 A. It is.

2 Q. So you would agree with me then all
3 of these 25 listed drugs are brand name opioids,
4 correct?

5 MS. DICKINSON: Objection to form.

6 A. Yes.

7 Q. And all of these are FDA approved
8 drugs, correct?

9 A. I'm not sure what Anexsia is. I've
10 never heard of that one. I would agree that
11 almost -- certainly almost all, if not all of
12 these, are opioids.

13 Q. And all of these are FDA approved
14 drugs, correct?

15 A. I believe so, yes.

16 Q. The document goes on to say "During
17 January, every pharmacist ordering the above
18 products on the Bergen system will be encouraged
19 to consider Oxycontin instead because of this
20 glimmer button."

21 Did I read that correctly?

22 A. Yes.

23 Q. So isn't the demand already there if
24 the licensed pharmacist is calling in to order an
25 opioid?

1 A. I'm sorry? What's your question?

2 Q. Isn't the demand already there if the
3 licensed pharmacist is calling in to order an
4 opioid?

5 MS. DICKINSON: Objection to form.

6 A. Not exactly.

7 Q. Why is that?

8 A. Because Oxycontin is a very different
9 drug from Tylenol with codeine. Tylenol with
10 codeine is acetaminophen with a low dosage of the
11 opioid. Oxycontin, one Oxycontin pill could have
12 50 -- the equivalent of 50 Tylenol with codeine in
13 it. Similarly for Ultram, another weak low dosage
14 opioid.

15 This idea that Oxycontin, this
16 extended release opioid that packs an enormous
17 dose of opioid, could be -- should be prescribed
18 instead of one of these competitor products, if
19 that happened, it was very likely this promotion
20 harmed people. It's much more likely to harm a
21 patient if you prescribe them Oxycontin than if
22 you prescribe them Tylenol with codeine.

23 Q. Oxycontin is oxycodone, correct?

24 A. Oxycontin is extended release
25 oxycodone. It comes in enormous doses and it's

1 meant to be taken around the clock. A patient who
2 takes Oxycontin can very quickly become dependent
3 or addicted.

4 Q. And Percocet is an oxycodone,
5 correct?

6 A. Correct. So the average Percocet
7 would have five milligrams of oxycodone in it.
8 Oxycontin comes in a dose with 80 milligrams of
9 oxycodone. They're not equivalent products.

10 Q. But they are all opioids, correct,
11 Doctor?

12 MS. DICKINSON: Counsel, he's not
13 finished with his answer. You guys are
14 talking over each other.

15 Doctor, please finish your answer and
16 counsel, can you give him a minute? You're
17 talking over him a lot.

18 A. Promoting Oxycontin where it's a
19 low-dosage opioid product that might have been
20 prescribed might have harmed patients. This is a
21 good example of marketing by a distributor that
22 had a harmful impact.

23 Q. But you do agree with me that all of
24 these drugs or at least most of these drugs are
25 opioids, correct?

1 A. To just say yes to that would be
2 misleading. They are not -- these drugs are not
3 all equivalent to Oxycontin. Oxycontin is an
4 extended relief oxycodone product that comes in an
5 extremely high dosage. Most of these or all
6 almost of them are immediate relief opioid
7 products that come in low dosages.

8 Q. You don't know if this was ever
9 implemented, correct?

10 MS. DICKINSON: Objection to form.

11 A. Based on the two pages that you
12 handed -- that you're asking me to comment on, I
13 can't say. I would hope that it wasn't, but I
14 think it's very likely that it was. And I --
15 maybe elsewhere in my report I cite examples -- I
16 do cite examples of promotions like this that were
17 implemented where there's a statement of work and
18 an invoice.

19 Q. But you're guessing that this was
20 implemented, correct? You don't have any
21 knowledge?

22 MS. DICKINSON: Objection to form.

23 Misstates his testimony.

24 A. Based on the two pages you're asking
25 me to give you an opinion about, it doesn't say

1 here. I believe that in my report I cite
2 examples -- and maybe this example -- of
3 promotions like this that were -- that I do know
4 were executed. I know they were executed because
5 there's data on their effectiveness commented on
6 internally.

7 Q. And you don't know how many West
8 Virginia pharmacists pushed on this glimmer button
9 and then ordered Oxycontin, correct?

10 A. I don't have data to tell me how
11 often that happened in the State of West Virginia.

12 Q. You cut put that aside, Doctor.
13 You state also in your report that
14 distributors sold services designed to increase
15 opioid use and another way that they did this was
16 by establishing programs on how pharmacists could
17 advise and reassure patients about opioids.

18 A. I'm sorry. Where are you reading
19 from?

20 Q. Page 14 of your report.

21 A. I'm sorry. Where on the page are
22 you?

23 Q. Right in the same sentence we were
24 just at, establishing programs on how pharmacists
25 could advise and reassure patients on opioids.

1 That's one more example that you give
2 that distributors sold services designed to
3 increase opioid use, correct?

4 A. I'm sorry. The example we just went
5 over was an example of a promotion. I'm not sure
6 what -- I'm sorry. Your question is --

7 Q. I'm simply asking you what you stated
8 your report, sir.

9 You stated that distributors sold
10 services designed to increase --

11 A. I'm sorry. I'm having --

12 Q. -- and one of the -- that's one of
13 your overall themes, is it not?

14 MS. DICKINSON: Objection to form.

15 A. Yes. I'm trying to see where exactly
16 you're reading from.

17 Q. Page 14 --

18 A. I'm on page 14.

19 Q. Same sentence that we were just at
20 before: Distributors did more than simply ship
21 orders, but rather culled services designed to
22 increase demand, including drafting template
23 letters, establishing programs on how pharmacists
24 could advise and reassure patients about opioids.

25 Correct?

1 A. Yes.

2 Q. Then you cite on page 15 ABDC's Plus
3 Care and Good Neighbor programs as examples of
4 this claim, correct?

5 MS. DICKINSON: Objection to form.
6 Lacks foundation.

7 A. I believe so. I'm not seeing where
8 it says that, but I -- that sounds right.

9 MS. VITALE: Can you please go to tab
10 ABDC eight? I'm going to mark as this
11 Exhibit ABDC 25.

12 (Whereupon, Exhibit 25 was marked for
13 identification.)

14 Q. This document shows that Bergen's
15 Plus Care involved Bergen Brunswick mailing a
16 packet to information to 1,800 community
17 pharmacists. The educational pieces designated
18 should include both the Plus Care logo and Good
19 Neighbor pharmacy logo.

20 Did I read that correctly?

21 A. Yes.

22 Q. Doctor, do you see where I read that?
23 Did I read it correctly?

24 A. Yes, you did.

25 Q. You do not know whether any West

1 Virginia pharmacist received these pamphlets
2 sitting here today, do you?

3 MS. DICKINSON: Objection to form.

4 A. I don't have the list of the 1,800
5 pharmacies that were targeted in front of me. The
6 answer is I don't know.

7 Q. And sitting here today, you do not
8 have any evidence of West Virginia pharmacists who
9 read and then reassured patients about opioids,
10 correct?

11 MS. DICKINSON: Objection to form.

12 A. I do have evidence that West Virginia
13 pharmacies and pharmacists were exposed to these
14 messages.

15 Q. So are you changing your testimony
16 that you just gave that you said you did not know
17 whether any West Virginia pharmacists received
18 these pamphlets?

19 A. I'm sorry. I thought you were asking
20 in general. You're talking about --

21 Q. No, I'm asking --

22 MS. DICKINSON: Counsel, counsel,
23 you've got to slow down. He's not even able
24 to get out his answer when you're asking the
25 next question. I know you don't have a lot

1 of time, but that's not his fault, so let him
2 answer the question.

3 Go ahead, Doctor. Try to finish your
4 answer.

5 A. So I'm sorry. I thought you were
6 asking me about in general.

7 On this specific promotion that
8 you're asking me about, I believe there's more --
9 I may have cited other examples of this Plus Care
10 promotion in my report. I think there's more to
11 the email exchange than this single page, if I
12 remember correctly. But based on this particular
13 page, what I can tell is that 1,800 pharmacies in
14 the United States were targeted and don't have the
15 list of pharmacies, so I can't say how many of
16 those 1,800 or if any of those 1,800 were in West
17 Virginia, but I do have evidence that West
18 Virginia pharmacies were exposed to these
19 promotions.

20 Q. When you say these promotions, you
21 mean these types of promotions? You don't have
22 evidence they were exposed to this particular
23 promotion, correct?

24 A. I may in my report, but you're right,
25 I am speaking about these types of promotions.

1 Q. Okay. You can put that aside. Thank
2 you.

3 You're aware that ABDC distributes
4 insulin, flu vaccine, blood pressure medication
5 and other non-opioid prescription medication to
6 its pharmacy customers, correct?

7 MS. DICKINSON: Objection to form.

8 A. Correct.

9 Q. You have no idea what percentage of
10 the company's distribution relates to other
11 life-saving medication, correct?

12 MS. DICKINSON: Objection to form.

13 Lacks foundation.

14 A. I'm sure I don't have a full
15 accounting of all of the different products that
16 AmerisourceBergen distributes.

17 Q. Now, you also claim in your report
18 that -- excuse me -- defendants promoted opioids
19 through core marketing techniques such as email
20 and fax blast, direct mail promotion, web
21 promotion, banner advertising, home page
22 advertising on defendant's home pages and even
23 telemarketing.

24 Could you go to page 40 of your
25 report, footnote 138, so you have the reference?

1 And you cite as an example of this
2 a --

3 MS. DICKINSON: Counsel, I don't know
4 if he's there yet. I'm certainly not. Can
5 you give us a second?

6 MS. VITALE: Page 40, footnote 138.

7 MS. DICKINSON: Okay. I'm there.
8 Doctor, have you found that?

9 A. Yes. I just want to see -- I can see
10 where it says footnote 138. I just want to read
11 the sentence that cites 138.

12 Okay. I'm with you.

13 Q. You cite a sell sheet for
14 Mallinckrodt's generic fentanyl patch provided to
15 Amerisource customers in the footnote.

16 Do you see that?

17 A. Yes, I do.

18 MS. VITALE: Can you go to tab ABDC
19 12, please? I'm going to mark this as ABDC
20 Exhibit 26.

21 (Whereupon, Exhibit 26 was marked for
22 identification.)

23 THE WITNESS: Got it.

24 Q. On page one of this sell sheet that
25 was provided to Amerisource customers, under

1 Indications and Usage, it reads "Because of the
2 risk of addiction, abuse and misuse with opioids,
3 even at recommended doses, and because of the
4 greater risks of overdose and death with extended
5 release opioid formulations, reserve fentanyl
6 transdermal system for use in patients for whom
7 alternative treatment options, for example,
8 non-opioid analgesics or immediate-release
9 opioids, are ineffective, not tolerated or would
10 be otherwise inadequate to provide sufficient
11 management of pain."

12 Did I read that correctly?

13 A. Yes.

14 Q. Then it says "Warning: Addiction,
15 abuse and misuse, life-threatening respiratory
16 depression, accidental exposure, neonatal opioid
17 withdrawal syndrome."

18 Did I read that correctly?

19 A. You did.

20 Q. Then it says "Addiction, Abuse and
21 Misuse: Fentanyl transdermal system exposes
22 patients and other users to the risk of opioid
23 addiction, abuse and misuse, which can lead to
24 overdose and death. Assess each patient's risk
25 prior to prescribing fentanyl transdermal system

1 and monitor all patients regularly."

2 Did I read that correctly?

3 A. Yes, I believe you did.

4 Q. You can put that aside, Doctor.

5 Do you know who Dr. Yingling is?

6 A. Say that name again.

7 Q. Dr. Kevin Yingling.

8 A. It sounds familiar.

9 Q. Are you aware that Dr. Yingling, who
10 is the Chairman of the Board of Director at Cabell
11 Huntington Hospital testified in this litigation
12 that he prescribed opioids and even increased the
13 rate at which he prescribed opioid medications
14 when he was in private practice?

15 Are you aware of that?

16 A. I'm not sure. I mean, I reviewed
17 thousands of pages of documents. Off the top of
18 my head, I can't recall whether or not I reviewed
19 his testimony.

20 Q. So are you saying that Dr. Yingling
21 was duped or easily manipulated into prescribing
22 opioids to his patients?

23 MS. DICKINSON: Objection to form.

24 Lacks foundation.

25 A. Can you read me his testimony again?

1 Q. He testified that he prescribed
2 opioids and increased the rate at which he
3 prescribed opioid medications when he was in
4 private practice.

5 MS. DICKINSON: Objection to form.

6 Lacks foundation.

7 A. I can't answer your question based on
8 I don't know who he treated. Was he working in
9 palliative care? If he was prescribing opioids to
10 patients who shouldn't have been getting opioids
11 and assuming he intended to be helping these
12 patients, then I would say he was influenced by
13 this campaign that resulted in the dramatic change
14 in opioid prescribing. I don't know him, but I
15 know many smart and well-meaning clinicians who
16 were influenced by this campaign.

17 Q. Do you know Dr. Kilkenney?

18 A. The name is familiar.

19 Q. Are you aware that Dr. Kilkenney, a
20 Physician Director of Cabell Huntington Hospital,
21 testified he prescribed opioids to his patients in
22 private practice?

23 MS. DICKINSON: Objection to form.

24 Lacks foundation.

25 A. I don't recall his specific

1 testimony.

2 Q. He also testified that he prescribed
3 opioids because he felt the benefit of opioid
4 medication outweighed the risk for that particular
5 patient.

6 Are you aware of that?

7 MS. DICKINSON: Objection to form.

8 Lacks foundation.

9 Counsel, he just testified he hasn't
10 reviewed his testimony.

11 It calls for speculation.

12 MS. VITALE: You can answer.

13 A. I haven't reviewed his testimony.
14 What I can tell you is that I would expect that
15 any clinician who is well intended is only going
16 to prescribe a medicine or recommend a surgical
17 intervention or any treatment if they believe that
18 the benefits outweigh the risks to the patient
19 that they're treating.

20 Unfortunately, when it comes to
21 opioids, in many cases, clinicians don't weigh the
22 risk versus benefit appropriately because they
23 are misinformed.

24 Q. So do you think Dr. Kilkenney was
25 writing these prescriptions because a pharmacist

1 who had a pamphlet told him to do so?

2 MS. DICKINSON: Objection to form.

3 Lacks foundation.

4 Calls for speculation.

5 Counsel, I don't know where you're
6 going with this, but you haven't laid a
7 foundation that he's even seen the testimony,
8 so you can maybe ask this one more question
9 about Kilkenny, but I don't know it's going
10 to get you and you've got three minutes.

11 So go ahead, Doctor, if you can even
12 begin to answer that question.

13 A. You were asking me about why a doctor
14 prescribed in a particular way. It's a doctor who
15 I don't believe I ever met. I don't recall
16 reviewing this doctor's testimony, I can't
17 really --

18 THE COURT REPORTER: Doctor, I'm
19 sorry, but I can't hear you.

20 A. I'm sorry. I can't -- I'm being
21 asked -- you're asking me why a particular doctor
22 prescribed a particular medication. I don't know
23 this doctor, I don't know who -- this doctor
24 patients, I don't recall reviewing this doctor's
25 testimony. I have absolutely no idea why this

1 doctor did or didn't do anything with any
2 particular patient or whether or not it was
3 appropriate or inappropriate. I don't know
4 anything about the doctor's patients.

5 MS. VITALE: Can you go to ABDC tab
6 25, please? I'm going to mark this as ABDC
7 Exhibit 27.

8 (Whereupon, Exhibit 27 was marked for
9 identification.)

10 Q. Doctor, my question is are you aware
11 in 2005 the West Virginia Board of Medicine
12 encouraged doctors to use prescription opioids to
13 treat chronic non-cancer pain?

14 A. Yes.

15 Q. If you go to the document -- It says
16 under the preamble, Section 1, last sentence, "For
17 the purposes of this policy, the inappropriate
18 treatment of pain includes nontreatment, under
19 treatment, over treatment and the continued use of
20 ineffective treatments."

21 Did I read that correctly?

22 A. I believe you did.

23 Q. On the second page, it says "The
24 Board recognizes that controlled substances,
25 including opioid analgesics, may be essential in

1 the treatment of acute pain due to trauma or
2 surgery and chronic pain whether due to cancer or
3 non-cancer origins."

4 Did I read that correctly?

5 A. You read it correctly.

6 Q. The last sentence in that same
7 paragraph says "Physicians should recognize that
8 tolerance and physical dependence are normal
9 consequences of sustained use of opioid analgesics
10 and are not the same as addiction."

11 Did I read that correctly?

12 A. I believe you are reading this
13 document correctly.

14 Q. Shouldn't the Board of Medicine be
15 held responsible for this pronouncement, since
16 this is a direct communication for physicians?

17 MS. DICKINSON: Objection to form.

18 Lacks foundation.

19 Counsel, I believe we just hit seven
20 hours, so if you need to ask one more
21 question or something that's fine, but
22 Doctor, go ahead and then we could wrap it
23 up.

24 A. That's a hard question to answer. I
25 would say I don't really hold the Board

1 responsible for being deceived. I believe the
2 Board was deceived. There are other statements
3 you didn't include.

4 For example, in this document is the
5 term "pseudoaddiction" and it lists as the
6 definition for pseudoaddiction the iatrogenic
7 syndrome relating from the misinterpretation of
8 relief seeking behaviors as though they are
9 drug-seeking behaviors that are commonly seen with
10 addiction. The relief seeking behaviors resolve
11 upon institution of effective analgesic therapy."

12 Where you see the word
13 "pseudoaddiction," it's like a fingerprint for the
14 opioids industries influence campaign, which was
15 extensive and influenced state medical boards,
16 largely through their trade association, the
17 federation of state medical boards.

18 Pseudoaddiction is a made up concept.
19 It was a term coined by David Haddox, Purdue
20 Pharma's medical director. It's a term that tells
21 prescribers to do exactly the opposite of what
22 they should do if they think a patient is
23 addicted.

24 What this is really saying is if your
25 patient looks like they might be addicted, give

1 them a higher dose. They look addicted because
2 you are under prescribing pain. This is a really
3 dangerous concept and it's a shame that the West
4 Virginia Medical Board helped disseminate that
5 concept, but I don't really blame them.

6 I think, like many in the medical
7 community, they believe that they were doing the
8 right thing, but they were influenced by an
9 industry funded campaign that the included the
10 distributors, your client.

11 Q. So just final question.

12 You believe the West Virginia Board
13 of Medicine was duped?

14 A. I believe that state medical boards
15 across the country were influenced by a campaign
16 that encouraged aggressive and inappropriate
17 prescribing. State medical boards across the
18 country were hearing that they were part of a
19 chilling effect in America. They were hearing
20 that patients were suffering needlessly because
21 doctors are too fearful of prescribing opioids
22 because of overblown fear of addiction and that we
23 could be much more compassionate if we prescribe
24 opioids more liberally. Eight medical boards fell
25 for it across the company. The opioid crisis

1 happened for a reason and this is one of the
2 reasons it happened. Yes. Eight medical boards
3 for influenced by the campaign that promoted
4 inappropriate prescribing.

5 MS. VITALE: Thank you, Doctor.

6 I appreciate your time.

7 No more questions.

8 MS. DICKINSON: I think we're out of
9 time, if the videographer and court reporter
10 want to close the record.

11 THE VIDEOGRAPHER: The time is
12 5:40 p.m. and we are off the record.

CERTIFICATION

I, SARA K. KILLIAN, RPR, CCR, do hereby certify that ANDREW KOLODNY, M.D., the witness whose examination under oath is hereinbefore set forth, was duly sworn, and that such deposition is a true record of the testimony given by such witness.

I FURTHER CERTIFY that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 4th day of September, 2020.

A handwritten signature in black ink, appearing to read "Sara K Killian". The signature is written in a cursive, flowing style with a horizontal line at the end.

SARA K. KILLIAN, RPR, CCR
Notary Public of the State of New York

Veritext Legal Solutions

1100 Superior Ave

Suite 1820

Cleveland, Ohio 44114

Phone: 216-523-1313

September 10, 2020

Andrew Kolodny

andrewjkolodny@gmail.com

Case Name: City Of Huntington v. Amerisourcebergen Drug Corporation,
Et Al.

Veritext Reference Number: 4241088 Deposition Date: 9/4/2020

Dear Sir/Madam:

Enclosed you will find a transcript of your deposition.

As the reading and signing have not been expressly
waived, please review the transcript and note any
changes or corrections on the errata sheet
included, indicating the page, line number, change and
reason for the change. Sign at the bottom of the sheet
in the presence of a notary and forward the errata sheet
back to us at the address shown above or email to
production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of
this letter, the reading and signing will be deemed waived.

Sincerely,

Production Department

NO NOTARY REQUIRED IN CA

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4241088

City Of Huntington v. Amerisourcebergen Drug Corp, Et Al.

DATE OF DEPOSITION: 9/4/2020

WITNESS' NAME: Andrew Kolodny

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have made no changes to the testimony as transcribed by the court reporter.

Date Andrew Kolodny

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal

this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4241088

City Of Huntington v. Amerisourcebergen Drug Corp, Et Al.

DATE OF DEPOSITION: 9/4/2020

WITNESS' NAME: Andrew Kolodny

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Andrew Kolodny

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

ERRATA SHEET
 VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 4241088

PAGE/LINE(S) / CHANGE / REASON

_____ Date _____ Andrew Kolodny

SUBSCRIBED AND SWORN TO BEFORE ME THIS _____

DAY OF _____, 20____.

 Notary Public

 Commission Expiration Date

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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